

## EXHIBIT 129

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IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

- - -

IN RE: NATIONAL : HON. DAN A. POLSTER  
PRESCRIPTION OPIATE :  
LITIGATION :  
:   
APPLIES TO ALL CASES : NO.  
: 1:17-MD-2804

- HIGHLY CONFIDENTIAL -

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

JANUARY 16, 2019

- - -

Videotaped sworn deposition of  
TRACEY L. NORTON, taken pursuant to  
notice, was held at BEST WESTERN LEHIGH  
VALLEY HOTEL & CONFERENCE CENTER, 300  
Gateway Drive, Bethlehem, Pennsylvania,  
beginning at 8:51 a.m., on the  
abovedate, before Margaret M. Reihl, a  
Registered Professional Reporter,  
Certified Shorthand Reporter, Certified  
Realtime Reporter, and Notary Public.

- - -

GOLKOW LITIGATION SERVICES  
877.370.3377 ph | 917.591.5672 fax  
deps@golkow.com

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<p>1 APPEARANCES:</p> <p>2 SEEGER WEISS LLP</p> <p>3 BY: DAVID BUCHANAN, ESQUIRE</p> <p>4 ELINA RAKHLIN, ESQUIRE</p> <p>5 SCOTT SIEGEL, PARALEGAL</p> <p>6 55 Challenger Road</p> <p>7 Ridgefield Park, New Jersey 07660</p> <p>8 (212) 584-7732</p> <p>9 erakhl@seegerweiss.com</p> <p>10 Representing the Plaintiffs</p> <p>11 MORGAN &amp; MORGAN</p> <p>12 BY: JAMES YOUNG, ESQUIRE</p> <p>13 RAYMOND TAMAYO, ESQUIRE (telephonic)</p> <p>14 TERESA DuBUISSON-MAI, ESQUIRE (telephonic)</p> <p>15 RENEE COOK, ESQUIRE (telephonic)</p> <p>16 SHAWKURA SHAW, ESQUIRE (telephonic)</p> <p>17 JENNIFER WILLIAMS, ESQUIRE (telephonic)</p> <p>18 76 Laura Street, Suite 1100</p> <p>19 Jacksonville, Florida 32202</p> <p>20 (904) 398-2722</p> <p>21 jyoung@forthepeople.com</p> <p>22 Representing the Plaintiffs</p> <p>23 MCCARTER &amp; ENGLISH</p> <p>24 BY: AMY M. VANNI, ESQUIRE</p> <p>1600 Market Street</p> <p>Suite 3900</p> <p>Philadelphia, Pennsylvania 19103</p> <p>(215) 979-3848</p> <p>avanni@mccarter.com</p> <p>- AND -</p> <p>BY: HAYLEY J. REESE, ESQUIRE</p> <p>405 N. King Street, 8th Floor</p> <p>Wilmington, Delaware 19801</p> <p>(302) 984-6308</p> <p>hreesee@mccarter.com</p> <p>Representing the Defendant Endo and</p> <p>the witness</p>	<p>1 APPEARANCES: (cont'd)</p> <p>2 JONES DAY</p> <p>3 BY: TAYLOR A. GOODSPEED, ESQUIRE</p> <p>4 555 California Street, 26th Floor</p> <p>5 San Francisco, California 94104-1500</p> <p>6 (415) 626-3939</p> <p>7 tgoodspeed@jonesday.com</p> <p>8 Representing the Defendant Walmart</p> <p>9 BARNES &amp; THORNBURG</p> <p>10 BY: WILLIAM J. LEEDER, III, ESQUIRE</p> <p>11 171 Monroe Avenue N.W.</p> <p>12 Suite 1000</p> <p>13 Grand Rapids, Michigan 49503-2694</p> <p>14 bleeder@btlaw.com</p> <p>15 Representing the Defendant H.D. Smith</p> <p>16 ALSO PRESENT:</p> <p>17 Sandra Di Iorio, Litigation Counsel</p> <p>18 Endo</p> <p>19 Kevin Frank, Videographer</p> <p>20 Bradley Smith, Trial Technician</p> <p>21 ---</p> <p>22</p> <p>23</p> <p>24</p>
Page 3	Page 5
<p>1 APPEARANCES: (cont'd)</p> <p>2 KIRKLAND &amp; ELLIS LLP</p> <p>3 BY: JENNIFER G. LEVY, ESQUIRE</p> <p>4 655 Fifteenth Street, N.W.</p> <p>5 Washington, D.C. 20005</p> <p>6 (202) 879-5211</p> <p>7 jenniferlevy@kirkland.com</p> <p>8 Representing the Defendant Allergan</p> <p>9 REED SMITH LLP</p> <p>10 BY: LOUIS W. SCHACK, ESQUIRE</p> <p>11 Three Logan Square</p> <p>12 1717 Arch Street, Suite 3100</p> <p>13 Philadelphia, Pennsylvania 19103</p> <p>14 (215) 851-8280</p> <p>15 lschack@reedsmith.com</p> <p>16 Representing the Defendant AmerisourceBergen</p> <p>17 FOLEY &amp; LARDNER LLP</p> <p>18 BY: KATY E. KOSKI, ESQUIRE</p> <p>19 111 Huntington Avenue</p> <p>20 Boston, Massachusetts 02199-7610</p> <p>21 (617) 342-4000</p> <p>22 kkoski@foley.com</p> <p>23 Representing the Defendant Anda</p> <p>24 MORGAN LEWIS &amp; BOCKIUS LLP</p> <p>BY: MARTHA A. LEIBELL, ESQUIRE</p> <p>200 South Biscayne Boulevard</p> <p>Suite 5300</p> <p>Miami, Florida 33131-2339</p> <p>(305) 415-3387</p> <p>martha.leibell@morganlewis.com</p> <p>Representing the Defendant Teva</p>	<p>1 TELEPHONIC APPEARANCES:</p> <p>2 TUCKER ELLIS LLP</p> <p>3 BY: SAVANNAH M. FOX, ESQUIRE</p> <p>4 950 Main Avenue, Suite 1100</p> <p>5 Cleveland, Ohio 44113</p> <p>6 (216) 696-3950</p> <p>7 savannah.fox@tuckerellis.com</p> <p>8 Representing the Defendants</p> <p>9 Janssen and J&amp;J</p> <p>10 WILLIAMS &amp; CONNOLLY LLP</p> <p>11 BY: JOSEPH S. BUSHUR, ESQUIRE</p> <p>12 725 Twelfth Street, N.W.</p> <p>13 Washington, D.C. 20005</p> <p>14 (202) 434-5013</p> <p>15 jbusher@wc.com</p> <p>16 Representing the Defendant,</p> <p>17 Cardinal Health</p> <p>18 ALLEGAERT BERGER &amp; VOGEL LLP</p> <p>19 BY: LUCY N. ONYEFORO, ESQUIRE</p> <p>20 111 Broadway, 20th Floor</p> <p>21 New York, New York 10006</p> <p>22 (212) 616-7050</p> <p>23 callegaert@abv.com</p> <p>24 Representing the Defendant,</p> <p>Rochester Drug Co-operative, Inc</p> <p>ALSTON &amp; BIRD LLP</p> <p>BY: JENNY A. HERGENROTHER, ESQUIRE</p> <p>1201 West Peachtree Street NW</p> <p>Atlanta, Georgia 30309</p> <p>(404) 881-4977</p> <p>jenny.hergenrother@alston.com</p> <p>Representing the Defendant Noramco</p>

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<p>1 EXHIBITS (cont'd)</p> <p>2 NO DESCRIPTION PAGE</p> <p>3 Par-</p> <p>4 Norton-24 E-mail dated 11/21/14,</p> <p>5 Subject, Secondary customers</p> <p>6 with attached letter</p> <p>7 [ENDO_HSGAC_0015838 to 5840] 445</p> <p>8 Par-</p> <p>9 Norton-25 E-mail dated 5/26/16,</p> <p>10 Subject, FW: Minutes from</p> <p>11 the Anti-Diversion Working</p> <p>12 Group Meeting - 10/8/2013</p> <p>13 with attachment</p> <p>14 [PAR_OPIOID MDL_000009576</p> <p>15 to 9579] 456</p> <p>16 Par-</p> <p>17 Norton-26 DEA Compliance Trip Report</p> <p>18 11/14/13</p> <p>19 [PAR_OPIOID MDL_0001252760</p> <p>20 to 2765] 470</p> <p>21 Par-</p> <p>22 Norton-27 E-mail dated 10/28/14,</p> <p>23 Subject, BuzzcoPDMA 9th</p> <p>24 Regional DEA Seminar -</p> <p>Agenda and Presentations</p> <p>with attachments</p> <p>[PAR_OPIOID MDL_0000016438</p> <p>to 6639] 480</p> <p>Par-</p> <p>Norton-28 Project Initiation Form (PIF)</p> <p>[HDS_Hernandez_00037 and</p> <p>HDS_MDL_00302301] 508</p> <p>Par-</p> <p>Norton-29 H D Smith Meeting Minutes</p> <p>9/7/16</p> <p>[HDS_MDL_00294884 to 4886] 528</p> <p>Par-</p> <p>Norton-30 E-mail dated 2/3/15, Subject</p> <p>CSOMP Analysis, with attachment</p> <p>[HDS_MDL_00407087 to 7088] 539</p>	<p>1 Congratulations, by the way?</p> <p>2 A. Thank you.</p> <p>3 Q. Have you ever been deposed</p> <p>4 before?</p> <p>5 A. I have not.</p> <p>6 Q. Okay. It's a Q and A. I'm sure</p> <p>7 you had a chance to meet with counsel before you</p> <p>8 came in today. It's, you know, a little more</p> <p>9 formal. Obviously, you see a videographer. You</p> <p>10 see a court reporter taking down everything that</p> <p>11 we say together. So it's going to be important</p> <p>12 that I do my best to wait until you're done</p> <p>13 answering to ask my questions and that you wait</p> <p>14 until my question is done to start answering.</p> <p>15 Fair?</p> <p>16 A. Absolutely.</p> <p>17 Q. Okay. The way this goes is</p> <p>18 there's going to be a written transcript, so if</p> <p>19 you don't understand the question, but you</p> <p>20 answer it anyway, the record is going to reflect</p> <p>21 that you understood the question. So if there's</p> <p>22 confusion in my questions, and there might be,</p> <p>23 I'm prone to confusing questions at times, just</p> <p>24 ask me to clarify, and I'll do my best to make</p>
Page 11	Page 13
<p>1 THE VIDEOGRAPHER: Good morning,</p> <p>2 we are now on the record. Today's date</p> <p>3 is January 16, 2019. The time is</p> <p>4 approximately 8:51 a.m. This is the</p> <p>5 videotaped deposition of Tracey</p> <p>6 Hernandez in the National Prescription</p> <p>7 Opiate Litigation. All counsel and</p> <p>8 parties present will be noted on the</p> <p>9 stenographic record.</p> <p>10 Will the court reporter please</p> <p>11 swear in the witness.</p> <p>12 ... TRACEY L. NORTON, having been</p> <p>13 duly sworn as a witness, was examined</p> <p>14 and testified as follows:</p> <p>15 BY MR. BUCHANAN</p> <p>16 Q. Good morning, ma'am. I think we</p> <p>17 just said this is the deposition of Tracey</p> <p>18 Hernandez, but I see from your updated resume</p> <p>19 that you're now Tracey Norton.</p> <p>20 A. Correct.</p> <p>21 Q. Please forgive me if at times I</p> <p>22 refer to you as Ms. Hernandez, because I think</p> <p>23 that's ingrained now in my mind, having looked</p> <p>24 at some of your documents over the years.</p>	<p>1 it better for you, okay?</p> <p>2 A. Okay, thank you.</p> <p>3 Q. Ms. Norton, I see that you are a</p> <p>4 person who over the course of your 25-plus years</p> <p>5 in the pharmaceutical industry have had a focus</p> <p>6 on compliance and DEA compliance in particular,</p> <p>7 is that fair?</p> <p>8 A. Yes, that's correct.</p> <p>9 MR. BUCHANAN: I've been handed</p> <p>10 an updated copy of your resume we've</p> <p>11 marked as Exhibit 1 to your deposition.</p> <p>12 (Document marked for</p> <p>13 identification as Par-Norton Deposition</p> <p>14 Exhibit No. 1)</p> <p>15 MR. BUCHANAN: Pass a copy back.</p> <p>16 Do you have one already, Counsel?</p> <p>17 MS. VANNI: I do, thank you.</p> <p>18 MR. BUCHANAN: There's one for</p> <p>19 you all to share and one for my</p> <p>20 colleague at the small table.</p> <p>21 BY MR. BUCHANAN</p> <p>22 Q. Is this the current version of</p> <p>23 your resume?</p> <p>24 A. Yes, it is.</p>

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<p style="text-align: right;">Page 14</p> <p>1 Q. You prepared it on your own?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And you didn't have any</p> <p>4 input from counsel into what to say and what not</p> <p>5 to say?</p> <p>6 MR. VANNI: Object to form.</p> <p>7 THE WITNESS: No.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. When I say you prepared it on</p> <p>10 your own, maybe somebody looked it over for you</p> <p>11 to help you --</p> <p>12 A. Years ago someone at like a</p> <p>13 resume service helped with some of it, but it's</p> <p>14 been modified several times by me since then.</p> <p>15 Q. Okay. Okay. They helped you get</p> <p>16 the framework together, but you own it?</p> <p>17 A. Correct.</p> <p>18 Q. You are comfortable with it, fair</p> <p>19 enough?</p> <p>20 A. Correct.</p> <p>21 Q. I want to focus with you</p> <p>22 principally on your time while you were with the</p> <p>23 Endo entities, I guess Qualitest and Endo,</p> <p>24 depending on the timeline and maybe Par.</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. And home -- just so we're clear,</p> <p>2 home is Bethlehem, Pennsylvania?</p> <p>3 A. Bethlehem.</p> <p>4 Q. Looks like where you finished up</p> <p>5 in Novartis, and let's just get the dates on</p> <p>6 that, you were there from '87 to 2002? I say</p> <p>7 Novartis, Ciba-Geigy.</p> <p>8 A. Correct.</p> <p>9 Q. '87 to 2002, you finished up in</p> <p>10 DEA, PDMA or in that department as a manager,</p> <p>11 fair?</p> <p>12 A. Yes.</p> <p>13 Q. And what is DEA?</p> <p>14 A. DEA is Drug Enforcement</p> <p>15 Administration.</p> <p>16 Q. And PDMA?</p> <p>17 A. Prescription Drug Marketing Act.</p> <p>18 Q. And you had some role for</p> <p>19 regulatory compliance in that group?</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: Yes.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. I see that you acted as a</p> <p>24 consultant -- I'm looking at the second bullet</p>
<p style="text-align: right;">Page 15</p> <p>1 You left in 2014, though,</p> <p>2 correct?</p> <p>3 A. Correct. I've never worked for</p> <p>4 Par.</p> <p>5 Q. So we'll focus on Endo/Qualitest,</p> <p>6 okay?</p> <p>7 I understand, though, before you</p> <p>8 joined Endo, you worked in the pharmaceutical</p> <p>9 industries?</p> <p>10 A. Yes, that's correct.</p> <p>11 MS. VANNI: Object to form.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. If we dial back in time, you've</p> <p>14 got -- you've helpfully put some page numbers</p> <p>15 page on there for us. I see page 3, started off</p> <p>16 with Novartis in '87. Was that out of school or</p> <p>17 out of high school?</p> <p>18 A. I worked out of high school and</p> <p>19 then at a bank and then to Novartis. Actually,</p> <p>20 it was Ciba-Geigy at the time.</p> <p>21 Q. Gotcha. Okay. And you worked</p> <p>22 there over in New Jersey over the river about 45</p> <p>23 minutes to an hour from here?</p> <p>24 A. About an hour and 15.</p>	<p style="text-align: right;">Page 17</p> <p>1 point -- "acted as a consultant to the division</p> <p>2 for issues associated with these regulations."</p> <p>3 Would these be DEA regulations?</p> <p>4 A. Correct.</p> <p>5 Q. Okay. "Quota, ARCOS,</p> <p>6 import/export, 222 forms, in-transit</p> <p>7 losses/thefts, returns/disposals, et cetera,"</p> <p>8 correct?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. And you've got other</p> <p>11 details on here as we go down, I think, to the</p> <p>12 fourth, fifth, six, bullet, something like that.</p> <p>13 "Supervised development of controlled drug</p> <p>14 reporting systems."</p> <p>15 Do you see that bullet?</p> <p>16 A. Correct, yes.</p> <p>17 Q. And these are systems that were</p> <p>18 within the company that would then report events</p> <p>19 or data to the various regulatory bodies,</p> <p>20 correct?</p> <p>21 MS. VANNI: Objection.</p> <p>22 THE WITNESS: To DEA.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. DEA, okay. The first you list is</p>

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<p style="text-align: right;">Page 18</p> <p>1     ARCOS; is that right?</p> <p>2     A.   Yes.</p> <p>3     Q.   That's a system that</p> <p>4     manufacturers and the DEA communicate back and</p> <p>5     forth about sales?</p> <p>6     MS. VANNI: Objection.</p> <p>7     THE WITNESS: And other things.</p> <p>8     BY MR. BUCHANAN:</p> <p>9     Q.   I'm sorry. Yeah. Could be the</p> <p>10    acquisition of controlled substances?</p> <p>11    A.   Yes.</p> <p>12    Q.   The disposition of controlled</p> <p>13    substances?</p> <p>14    A.   It's all transactions -- or most</p> <p>15    transactions with certain controlled substances.</p> <p>16    Q.   Okay. And -- or SOMs, what is</p> <p>17    SOMs?</p> <p>18    A.   Suspicious order monitoring.</p> <p>19    Q.   And that term may come up today</p> <p>20    more than ten times, so how do you use that</p> <p>21    acronym?</p> <p>22    A.   SOM.</p> <p>23    Q.   You do? Okay. So you supervised</p> <p>24    the development of controlled drug reporting</p>	<p style="text-align: right;">Page 20</p> <p>1     recall exactly when it transitioned from</p> <p>2     Ciba-Geigy to Novartis. So when I was</p> <p>3     the DEA PDMA manager, I had that</p> <p>4     responsibility.</p> <p>5     BY MR. BUCHANAN:</p> <p>6     Q.   Okay. So SOM was something that</p> <p>7     you were engaged with maybe more tangentially</p> <p>8     while you were at Ciba-Geigy/Novartis, fair?</p> <p>9     MS. VANNI: Objection.</p> <p>10    THE WITNESS: I'm sorry.</p> <p>11    BY MR. BUCHANAN:</p> <p>12    Q.   I'll let you describe it. I'm</p> <p>13    not trying to mischaracterize it in any way. It</p> <p>14    didn't sound like you had primary responsibility</p> <p>15    for Novartis' SOM system, fair?</p> <p>16    MS. VANNI: Objection.</p> <p>17    THE WITNESS: It was -- Novartis'</p> <p>18    SOM system was in place prior to my</p> <p>19    coming, and I maintained it and may have</p> <p>20    modified along the way, so yes.</p> <p>21    BY MR. BUCHANAN:</p> <p>22    Q.   Okay. And when we talk about</p> <p>23    SOMs, we're talking about a system for reporting</p> <p>24    orders, orders of concern, suspicious orders to</p>
<p style="text-align: right;">Page 19</p> <p>1     systems such as we talked about ARCOS briefly</p> <p>2     and then SOM.</p> <p>3     So while you were at Ciba-Geigy,</p> <p>4     you had responsibility for that system?</p> <p>5     MS. VANNI: Objection. You can</p> <p>6     answer.</p> <p>7     THE WITNESS: I'm not sure if --</p> <p>8     when the transition occurred from</p> <p>9     Ciba-Geigy to Novartis, so at</p> <p>10    Ciba-Geigy, probably not. I think that</p> <p>11    was prior. There was someone else in</p> <p>12    the role as -- that would head up that</p> <p>13    group, so I was provided input into it,</p> <p>14    but I wasn't the main person championing</p> <p>15    it.</p> <p>16    BY MR. BUCHANAN:</p> <p>17    Q.   Okay. So you had visibility to</p> <p>18    it, but not responsibility or exclusive</p> <p>19    responsibility for it?</p> <p>20    MS. VANNI: Objection.</p> <p>21    THE WITNESS: Yes. As you see</p> <p>22    it, like when I started as a regulatory</p> <p>23    analyst, that was basically at the time</p> <p>24    Ciba-Geigy. I don't know -- I don't</p>	<p style="text-align: right;">Page 21</p> <p>1     the DEA related to controlled substances, fair?</p> <p>2     MS. VANNI: Objection.</p> <p>3     THE WITNESS: Reporting</p> <p>4     suspicious orders.</p> <p>5     BY MR. BUCHANAN:</p> <p>6     Q.   To the DEA, correct?</p> <p>7     A.   Mm-hmm.</p> <p>8     Q.   And there's been regulatory</p> <p>9     frameworks around that for some time, true?</p> <p>10    MS. VANNI: Objection.</p> <p>11    THE WITNESS: Yes.</p> <p>12    BY MR. BUCHANAN:</p> <p>13    Q.   As a person in the industry for</p> <p>14    at least 25 years or now 30 years now, you've</p> <p>15    been aware of, if you will, statutory frameworks</p> <p>16    and regulatory frameworks around manufacturer</p> <p>17    and distributor obligations for suspicious order</p> <p>18    monitoring, correct?</p> <p>19    MS. VANNI: Objection.</p> <p>20    THE WITNESS: It's changed</p> <p>21    drastically over time, but, yes. The</p> <p>22    regulation itself has been the same, but</p> <p>23    the interpretation and application has</p> <p>24    changed drastically over the years.</p>

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<p style="text-align: right;">Page 22</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. And we'll circle back on that</p> <p>3 more specifically as we go through today, but to</p> <p>4 start with, I mean, the statute has been the</p> <p>5 same, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And a manufacturer and</p> <p>8 distributor has to maintain -- a manufacturer</p> <p>9 and distributor of controlled substances has to</p> <p>10 maintain effective controls against diversion,</p> <p>11 correct?</p> <p>12 MS. VANNI: Objection.</p> <p>13 THE WITNESS: Registrants have to</p> <p>14 maintain.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Fair enough. And a registrant</p> <p>17 who is a manufacturer, a registrant that is a</p> <p>18 distributor has to maintain effective controls</p> <p>19 against diversion, correct?</p> <p>20 A. Yes.</p> <p>21 Q. And I take it, then, during your</p> <p>22 time with Novartis -- Novartis was a registrant?</p> <p>23 A. Correct.</p> <p>24 Q. Okay. There are also obligations</p>	<p style="text-align: right;">Page 24</p> <p>1 to the company and to work to -- work to improve</p> <p>2 or to end ultimately to comply with those</p> <p>3 regulations.</p> <p>4 Q. And some of the things that you</p> <p>5 consider obviously as a compliance manager are</p> <p>6 the regulations themselves, right?</p> <p>7 A. Yes.</p> <p>8 Q. You consider how the DEA is</p> <p>9 applying or interpreting or enforcing those</p> <p>10 regulations?</p> <p>11 MS. VANNI: Objection.</p> <p>12 THE WITNESS: Yes. And the</p> <p>13 reason I say yes is because different</p> <p>14 local offices sometimes apply them</p> <p>15 differently, but, yes, overall.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. You go to industry conferences</p> <p>18 and you hear what others have to say about what</p> <p>19 they're doing to -- and how they're interpreting</p> <p>20 the regulations to ensure compliance?</p> <p>21 MS. VANNI: Objection.</p> <p>22 THE WITNESS: Yes, to a certain</p> <p>23 extent within confidentiality.</p> <p>24 BY MR. BUCHANAN:</p>
<p style="text-align: right;">Page 23</p> <p>1 under the regulations that have been passed by</p> <p>2 the DEA with regard to the monitoring and</p> <p>3 reporting of suspicious orders, correct?</p> <p>4 MS. VANNI: Objection.</p> <p>5 THE WITNESS: Yes, there's a</p> <p>6 regulation.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. Okay. And in your field, I've</p> <p>9 seen at various times that you've been</p> <p>10 characterized as a, quote, DEA compliance</p> <p>11 manager; would that be fair?</p> <p>12 A. Yes.</p> <p>13 Q. And when you -- is compliance a</p> <p>14 field?</p> <p>15 A. Yes.</p> <p>16 Q. Could you describe generally what</p> <p>17 compliance is, as a field?</p> <p>18 A. Well, there's a lot of different</p> <p>19 types of compliance. Are you referring</p> <p>20 specifically to DEA compliance?</p> <p>21 Q. I am.</p> <p>22 A. Okay. The goal of individuals in</p> <p>23 those positions is to become familiar with the</p> <p>24 DEA regulations and to apply those regulations</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. And we'll probably have a chance</p> <p>2 to talk about some of that today. You've been</p> <p>3 on various committees, antidiversion working</p> <p>4 groups, various distributor associations,</p> <p>5 various manufacturer associations where you've</p> <p>6 gone and attended and received input as to I'll</p> <p>7 say antidiversion and SOM practices, fair?</p> <p>8 MS. VANNI: Objection.</p> <p>9 THE WITNESS: Well,</p> <p>10 antidiversion, yes, yes.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. In fact, you've presented at</p> <p>13 them, correct?</p> <p>14 A. Yes.</p> <p>15 Q. So that's one of the ways in</p> <p>16 which those in the industry get information</p> <p>17 about, if you will, state-of-the-art compliance,</p> <p>18 state-of-the-art SOM practices, state-of-the-art</p> <p>19 antidiversion practices, true?</p> <p>20 MS. VANNI: Objection.</p> <p>21 THE WITNESS: Yes and no. A lot</p> <p>22 of things aren't shared because of the</p> <p>23 confidentiality, so I always say I want</p> <p>24 to hear it from the horse's mouth, I</p>

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<p style="text-align: right;">Page 26</p> <p>1 want to hear it from DEA. I do take</p> <p>2 into consideration, but ultimately any</p> <p>3 changes I implement would be based on</p> <p>4 things that I would hear from the DEA.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. And as a manufacturer, as a</p> <p>7 distributor of controlled substances, there's</p> <p>8 also just the general responsibility to ensure</p> <p>9 that your product isn't getting to places where</p> <p>10 it's not supposed to get, right?</p> <p>11 MS. VANNI: Objection.</p> <p>12 THE WITNESS: Yes.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. And you recognize that?</p> <p>15 MS. VANNI: Objection.</p> <p>16 THE WITNESS: It's part of the</p> <p>17 regulation.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. And part of your obligation as</p> <p>20 the manufacturer distributor?</p> <p>21 MS. VANNI: Objection.</p> <p>22 THE WITNESS: To follow the</p> <p>23 regulations.</p> <p>24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 28</p> <p>1 issues while you were at Watson with regard to</p> <p>2 Watson's DEA compliance?</p> <p>3 MS. VANNI: Objection.</p> <p>4 THE WITNESS: Not that I can</p> <p>5 recall.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. Did you ever have any issues</p> <p>8 while you were at Watson with regard to Anda's</p> <p>9 compliance?</p> <p>10 MS. VANNI: Objection.</p> <p>11 THE WITNESS: I was not -- I</p> <p>12 didn't have responsibility for Anda. I</p> <p>13 was consulted on occasion and did help</p> <p>14 out at certain points, but it was not my</p> <p>15 ultimate responsibility.</p> <p>16 BY MS. DICKINSON:</p> <p>17 Q. I mean, they got called in to the</p> <p>18 DEA for some issues, right?</p> <p>19 A. Yes.</p> <p>20 Q. Were you the one responsible for</p> <p>21 the oversight of that problem before it was</p> <p>22 brought to the DEA?</p> <p>23 MS. KOSKI: Object to form.</p> <p>24 THE WITNESS: No, I had no</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. Okay. Let's look, then, at where</p> <p>2 you went after -- after Novartis. You went to</p> <p>3 Watson; is that right?</p> <p>4 A. Yes, that's correct.</p> <p>5 Q. And if I understand correctly</p> <p>6 during your time at Watson, there was an</p> <p>7 acquisition of another company Anda?</p> <p>8 A. Anda, yes.</p> <p>9 Q. Is that how it's pronounced Anda,</p> <p>10 it's not ANDA?</p> <p>11 A. Yeah. ANDA would refer more to</p> <p>12 an FDA acronym.</p> <p>13 Q. I thought that was why they did</p> <p>14 that. But okay. It's Anda. Thank you.</p> <p>15 So Watson acquired Anda and</p> <p>16 during your tenure at Watson?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. I just need to draw a</p> <p>19 distinction between the companies.</p> <p>20 With regard to Watson, did you</p> <p>21 have a role in responsibility for DEA</p> <p>22 compliance?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Did you ever have any</p>	<p style="text-align: right;">Page 29</p> <p>1 responsibility for Anda up until that</p> <p>2 point.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. Okay. So as I understand the</p> <p>5 timeline, you're at Watson from 2002 to 2009.</p> <p>6 You finish as the director of controlled</p> <p>7 substances compliance. Within that function,</p> <p>8 you had responsibility for suspicious order</p> <p>9 monitoring for Watson, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And then Watson at a point in</p> <p>12 time acquired Anda, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Anda got called in by the DEA for</p> <p>15 some violations, fair?</p> <p>16 MS. KOSKI: Object to form.</p> <p>17 THE WITNESS: Not for violations,</p> <p>18 no.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. Okay. They had a sit-down with</p> <p>21 the DEA?</p> <p>22 MS. KOSKI: Object to form.</p> <p>23 THE WITNESS: It was part of the</p> <p>24 distributor initiative.</p>

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<p style="text-align: right;">Page 30</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. And let's make sure we understand</p> <p>3 your role in that.</p> <p>4 Shortly after Watson purchased</p> <p>5 Anda, Anda was summoned to the DEA as a result</p> <p>6 of their lack of a robust SOM program, correct?</p> <p>7 MS. KOSKI: Object to form.</p> <p>8 THE WITNESS: No, that's not</p> <p>9 correct. DEA -- DEA was -- had</p> <p>10 initiated what they termed a distributor</p> <p>11 initiative, and they called all</p> <p>12 distributors at different times to the</p> <p>13 headquarters office to talk about sales</p> <p>14 of their product.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Okay. So I'm not sure that we</p> <p>17 can pin down the date, or at least in my</p> <p>18 examination we won't be pinning down the date,</p> <p>19 but at a point in time when you were at Watson,</p> <p>20 do you remember roughly when this was that you</p> <p>21 got called in with Anda to meet with the DEA?</p> <p>22 MS. KOSKI: Object to form.</p> <p>23 THE WITNESS: I don't. I would</p> <p>24 assume closer to the time I left, but I</p>	<p style="text-align: right;">Page 32</p> <p>1 She was a Qualitest employee.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Yeah, I'm thinking of you in the</p> <p>4 Endo family of companies, Endo being -- Endo was</p> <p>5 the owner of Qualitest?</p> <p>6 A. Endo was the owner, but there was</p> <p>7 a separate business from Qualitest, and I was</p> <p>8 not -- not responsible for that business. I</p> <p>9 handled just Qualitest really for the most part.</p> <p>10 Q. Okay. All right, fair. So this</p> <p>11 is during your time at Qualitest, then, shortly</p> <p>12 before you left. And looks like about two</p> <p>13 months before -- you left Qualitest in November</p> <p>14 of 2014; is that right?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. It's an e-mail between</p> <p>17 somebody in HR at H.D. Smith and yourself.</p> <p>18 "Please call Tracey at the phone number at"</p> <p>19 blank. "She is expecting your call right now.</p> <p>20 Thanks for the last minute."</p> <p>21 There's two attachments. One is</p> <p>22 your resume.</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 31</p> <p>1 don't know for sure.</p> <p>2 (Document marked for</p> <p>3 identification as Par-Norton Deposition</p> <p>4 Exhibit No. 2.)</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Ma'am, I'm passing over what</p> <p>7 we're marking as Exhibit 2 to your deposition.</p> <p>8 I have a few more questions before we get into</p> <p>9 that, but you will have a chance to review that</p> <p>10 at the appropriate time.</p> <p>11 So you were at Watson, just to</p> <p>12 confirm, until 2009?</p> <p>13 A. Yes.</p> <p>14 Q. And do you remember roughly how</p> <p>15 soon before you left Watson that this -- or when</p> <p>16 relative to your departure from Watson this</p> <p>17 meeting with Anda and the DEA occurred?</p> <p>18 A. I do not recall.</p> <p>19 Q. Okay. Let's look now at</p> <p>20 Exhibit 2 to your deposition. This is a</p> <p>21 document during your time at Endo. It was</p> <p>22 produced to us by, I think, H.D. Smith.</p> <p>23 MS. VANNI: Counsel, I just want</p> <p>24 to clarify she was not an Endo employee.</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. Another is a document entitled</p> <p>2 "SOMs Experience"?</p> <p>3 A. Mm-hmm.</p> <p>4 Q. Do you recognize this document</p> <p>5 "Tracey Hernandez SOM Experience"?</p> <p>6 A. I do. It was specifically</p> <p>7 requested as part of the interview process.</p> <p>8 Q. Okay. So you had to assemble</p> <p>9 something to share with H.D. Smith as part of</p> <p>10 this interview process?</p> <p>11 A. Yes, to prove my experience with</p> <p>12 SOM.</p> <p>13 Q. Okay. And so what you did in</p> <p>14 doing so is you listed your relevant SOM</p> <p>15 experience at various entities that you'd worked</p> <p>16 with over the years, fair?</p> <p>17 A. Yes.</p> <p>18 Q. For example, with Ciba-Geigy, you</p> <p>19 list that you reviewed and submitted monthly</p> <p>20 suspicious order monitoring reports to the DEA</p> <p>21 for review. You note back then suspicious</p> <p>22 orders were based solely on the customer's order</p> <p>23 frequency pattern and volume, and then you</p> <p>24 notified customer service based on the DEA</p>

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<p style="text-align: right;">Page 34</p> <p>1 register notice or conversations if there were</p> <p>2 customers that were high-risk customers, right?</p> <p>3 A. Yes.</p> <p>4 Q. And that was something that was</p> <p>5 reasonable to do at that time, to comply with</p> <p>6 your obligation as a manufacturer?</p> <p>7 MS. VANNI: Object to form.</p> <p>8 THE WITNESS: Yes, it was.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. And so one of the things you were</p> <p>11 doing while at Ciba-Geigy or Novartis was, you</p> <p>12 know, monitoring customers to see if customers</p> <p>13 were, in fact, high-risk customers, right?</p> <p>14 MS. VANNI: Objection.</p> <p>15 THE WITNESS: Monitoring</p> <p>16 customers for suspicious orders.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Right. Which you note here in</p> <p>19 your writing. And these are your words,</p> <p>20 correct?</p> <p>21 A. Yes.</p> <p>22 Q. "If a customer was deemed a high</p> <p>23 risk and should be discontinued."</p> <p>24 Do you see that at the bottom?</p>	<p style="text-align: right;">Page 36</p> <p>1 Do you see that?</p> <p>2 A. So the Federal Registers would</p> <p>3 be --</p> <p>4 Q. I'm sorry, I just need to make</p> <p>5 sure that you --</p> <p>6 A. Yes, I see that.</p> <p>7 Q. Okay. And if you're -- what</p> <p>8 you're doing there is you're looking to external</p> <p>9 sources, in this case, the Federal Register</p> <p>10 notices or conversations with the DEA to</p> <p>11 determine and to ensure that your customers are</p> <p>12 not high risk, right?</p> <p>13 MS. VANNI: Objection.</p> <p>14 THE WITNESS: Yes. If a customer</p> <p>15 appeared in a Federal Register notice</p> <p>16 and had a license suspended or had</p> <p>17 action taken against them, I would</p> <p>18 contact them to -- customer service to</p> <p>19 make sure that they weren't, in fact, a</p> <p>20 customer that we were shipping to.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Right. So when you became aware</p> <p>23 that there were customers that were engaged in</p> <p>24 problematic activities, you notified customer</p>
<p style="text-align: right;">Page 35</p> <p>1 A. On Ciba-Geigy?</p> <p>2 Q. Yes.</p> <p>3 A. Yes.</p> <p>4 Q. And so you understood, at least</p> <p>5 during your time at Novartis and during your</p> <p>6 time at Ciba-Geigy, that was one of the</p> <p>7 obligations of a manufacturer distributor?</p> <p>8 MS. VANNI: Objection.</p> <p>9 THE WITNESS: To notify for</p> <p>10 suspicious orders, yes.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. And to monitor for customers that</p> <p>13 were a high risk and who should be discontinued,</p> <p>14 correct?</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: My definition of a</p> <p>17 high risk would mean that they have</p> <p>18 suspicious orders.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. Okay. Well, in order to -- what</p> <p>21 you say you are going to do here is notify</p> <p>22 customer service based on -- I think you say DEA</p> <p>23 Federal Register notices or conversations with</p> <p>24 DEA if a customer was deemed high risk.</p>	<p style="text-align: right;">Page 37</p> <p>1 service so customer service ceases activity or</p> <p>2 you got comfort that we weren't doing business</p> <p>3 with them or Ciba-Geigy wasn't doing business</p> <p>4 with them?</p> <p>5 MS. VANNI: Objection.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. And for clarity, ma'am, what was</p> <p>9 the period of time when you were working at</p> <p>10 Ciba-Geigy and Novartis?</p> <p>11 A. From 1987 to 2002.</p> <p>12 Q. Okay. And you understood that</p> <p>13 part of the role and obligation of Ciba-Geigy or</p> <p>14 Novartis as a registrant was to maintain</p> <p>15 effective controls against diversion, fair?</p> <p>16 A. Yes, that's --</p> <p>17 MS. VANNI: Objection.</p> <p>18 THE WITNESS: -- part of the DEA</p> <p>19 regulation.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. That's the statute, actually?</p> <p>22 A. Mm-hmm.</p> <p>23 Q. Yes?</p> <p>24 A. Yes.</p>

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<p style="text-align: right;">Page 38</p> <p>1 Q. Okay. And one of the ways that</p> <p>2 you did that at that point in time was by</p> <p>3 notifying customer service of high-risk</p> <p>4 customers, correct?</p> <p>5 MS. VANNI: Object to form.</p> <p>6 THE WITNESS: Yes. It was not a</p> <p>7 requirement that I notify them, but,</p> <p>8 obviously, I don't want to ship to</p> <p>9 someone who has a suspended license or</p> <p>10 has issues.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Whether it was a requirement or</p> <p>13 not, that's what you did at that point in time</p> <p>14 as part of you executing your role and function</p> <p>15 in DEA compliance for Ciba-Geigy and Novartis,</p> <p>16 fair?</p> <p>17 MS. VANNI: Objection.</p> <p>18 THE WITNESS: Yes, always tried</p> <p>19 to go above and beyond, yes.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Okay. And it was reasonable to</p> <p>22 do that, right?</p> <p>23 MS. VANNI: Objection.</p> <p>24 THE WITNESS: Mm-hmm.</p>	<p style="text-align: right;">Page 40</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And those are your words</p> <p>3 certainly in characterizing your experience at</p> <p>4 Watson with regard to Anda and that particular</p> <p>5 DEA interaction, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And what you note after that, and</p> <p>8 I think to -- well, I'll ask you this. What you</p> <p>9 note after that was "I did not support Anda from</p> <p>10 a DEA perspective, as they had come to Watson</p> <p>11 with their own DEA person. However, I was asked</p> <p>12 to be their DEA representative for the meeting</p> <p>13 in HQ. I went with legal and the individual who</p> <p>14 at the time was the president of Anda. DEA</p> <p>15 presented and provided a binder, as they have</p> <p>16 done for most companies at this point. However,</p> <p>17 in Anda's case, the DEA meeting was for cause,</p> <p>18 and immediate action was required."</p> <p>19 Did I read that correctly?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. So this particular meeting</p> <p>22 with regard to Anda was different than the other</p> <p>23 meetings that you were aware that were happening</p> <p>24 in the industry at that point in time, correct?</p>
<p style="text-align: right;">Page 39</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Is that a yes?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. It looks like while you</p> <p>5 were at Watson, you didn't have any interactions</p> <p>6 concerning the SOM program in terms of</p> <p>7 deficiencies in your SOM program relevant to the</p> <p>8 Watson part of the business, fair?</p> <p>9 A. Yes.</p> <p>10 Q. Then you note "However, Watson</p> <p>11 purchased Anda."</p> <p>12 Do you see that in the middle of</p> <p>13 the page, the middle of the Watson page?</p> <p>14 A. Yes.</p> <p>15 Q. It says "However, Watson</p> <p>16 purchased Anda and shortly afterward, Anda was</p> <p>17 summoned to DEA a result of their lack of a</p> <p>18 robust SOM program."</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And that was the reference</p> <p>22 I mentioned five, ten minutes ago with regard to</p> <p>23 why you went to see the DEA.</p> <p>24 Do you see that, ma'am?</p>	<p style="text-align: right;">Page 41</p> <p>1 MS. KOSKI: Object to form.</p> <p>2 THE WITNESS: It was -- I'm</p> <p>3 sorry, can you repeat that?</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. This particular meeting with</p> <p>6 regard to Anda was different than the other</p> <p>7 meetings that you were aware of that were</p> <p>8 happening between DEA and the industry at that</p> <p>9 point in time, correct?</p> <p>10 MS. KOSKI: Objection.</p> <p>11 THE WITNESS: It was the same</p> <p>12 type of meeting. It was a distributor</p> <p>13 initiative. They reviewed the same type</p> <p>14 of data. The individuals that we met</p> <p>15 with presented it a little differently</p> <p>16 than other meetings I had been at.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Okay. This particular meeting as</p> <p>19 you characterized it in summarizing your SOM</p> <p>20 experience at and Watson -- and, again, we're</p> <p>21 referring at the meeting with DEA and Anda --</p> <p>22 you characterize it as a meeting for cause,</p> <p>23 correct?</p> <p>24 A. I did characterize it that way.</p>

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<p style="text-align: right;">Page 42</p> <p>1 However, there was no DEA violation. There was</p> <p>2 no action taken by DEA against Anda. It was a</p> <p>3 meeting to share information, and that was also</p> <p>4 my first experience with a distributor.</p> <p>5 Everything up to that point had been more on the</p> <p>6 manufacturing side, so to me at the time, it was</p> <p>7 spun a little bit differently.</p> <p>8 Q. Okay. I understand that this</p> <p>9 meeting was different than prior meetings you</p> <p>10 had had kind of with your manufacturer hat on.</p> <p>11 A. Right.</p> <p>12 Q. But with regard to this meeting,</p> <p>13 and you wrote this, to be clear, some five</p> <p>14 years, six years after the meeting, right?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. And the way you</p> <p>17 characterized it with the benefit of hindsight</p> <p>18 and looking backward was a meeting for cause</p> <p>19 with immediate action required, correct?</p> <p>20 A. Yes. I think you need to take</p> <p>21 into context the purpose of the document,</p> <p>22 though. You know, I'm trying to get a job, so</p> <p>23 obviously I'm trying to make myself look very</p> <p>24 good to this company and to kind of put forth</p>	<p style="text-align: right;">Page 44</p> <p>1 THE WITNESS: I actually don't</p> <p>2 know what they had. What was -- and I</p> <p>3 also didn't know their customer base.</p> <p>4 Since I hadn't worked with them up to</p> <p>5 that point, I was told that I, you know,</p> <p>6 was not to handle Anda from a DEA</p> <p>7 perspective, that was someone else's</p> <p>8 responsibility. So I was pulled into</p> <p>9 the meeting really without having any</p> <p>10 background on the company.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Right. You are a DEA compliance</p> <p>13 person. Watson has just acquired Anda. There's</p> <p>14 a situation that has occurred that apparently is</p> <p>15 being seen as a serious situation because the</p> <p>16 president as a company knew, correct?</p> <p>17 A. He was very concerned, yes.</p> <p>18 Q. And Anda grabs you from the</p> <p>19 Watson side, please come and sit next to us in</p> <p>20 this meeting while we take the bullets we're</p> <p>21 going to take on this?</p> <p>22 MS. KOSKI: Object to form.</p> <p>23 THE WITNESS: They actually asked</p> <p>24 me to come because of my -- because I</p>
<p style="text-align: right;">Page 43</p> <p>1 that, you know, this company needed me at this</p> <p>2 time, and I stepped in and helped out and was</p> <p>3 able to resolve an issue, so...</p> <p>4 Q. Well, yeah, and I suppose, you</p> <p>5 know, thank you for, I would say, being candid</p> <p>6 and reflecting the context in which this was</p> <p>7 prepared, but you were also saying, weren't you,</p> <p>8 that the problems that Anda had were not mine?</p> <p>9 MS. KOSKI: Object to form.</p> <p>10 THE WITNESS: They became mine.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Right. We could read this, and</p> <p>13 it says "Watson had no issues with DEA regarding</p> <p>14 their SOMs program during my seven-year tenure."</p> <p>15 A. Mm-hmm.</p> <p>16 Q. "However, Watson purchased Anda</p> <p>17 and shortly afterward, Anda was summoned to DEA</p> <p>18 as a result of their lack of a robust SOM</p> <p>19 program."</p> <p>20 Did I read that correctly?</p> <p>21 A. Yes.</p> <p>22 Q. Was that true that they did not</p> <p>23 have a robust SOM program?</p> <p>24 MS. KOSKI: Object to form.</p>	<p style="text-align: right;">Page 45</p> <p>1 knew the people that had called them to</p> <p>2 the meeting. I had interacted with them</p> <p>3 previously on multiple occasions and</p> <p>4 they had -- had reached out to me. So I</p> <p>5 think they felt more comfortable that I</p> <p>6 would, you know, have a good working</p> <p>7 relationship with them and would --</p> <p>8 would help the meeting to go smoothly.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Okay. And so in that context,</p> <p>11 how you characterized it at least for purposes</p> <p>12 of reflectively, looking back at that time, was</p> <p>13 that they were summoned to the DEA as a result</p> <p>14 of their lack of a robust SOM program and that</p> <p>15 the DEA meeting was for cause and immediate</p> <p>16 action was required, those were some reflections</p> <p>17 that you noted on this particular meeting, fair,</p> <p>18 ma'am?</p> <p>19 A. That's what I noted in the</p> <p>20 document, yes.</p> <p>21 Q. And then you said after that, you</p> <p>22 worked with the president and "we reviewed</p> <p>23 numerous customers and cut many"; is that right?</p> <p>24 A. Yes, probably too many.</p>



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<p style="text-align: right;">Page 46</p> <p>1 Q. So during the time that you were</p> <p>2 at Watson -- and you left there when, ma'am?</p> <p>3 A. 2009.</p> <p>4 Q. So prior to 2009, during your</p> <p>5 time with Watson in connection with your role</p> <p>6 and oversight of Anda, when you started to work</p> <p>7 with the president to actually look at the</p> <p>8 customers in a manner like you had looked at</p> <p>9 customers at Novartis and Ciba-Geigy, you cut</p> <p>10 many customers, correct?</p> <p>11 MS. KOSKI: Object to form.</p> <p>12 THE WITNESS: It wasn't in the</p> <p>13 same manner and, again, because I didn't</p> <p>14 know their business, the president</p> <p>15 really took it upon himself. At that</p> <p>16 meeting, DEA had -- one of the</p> <p>17 individuals at DEA had thrown out a</p> <p>18 number as far as dosage forms, and they</p> <p>19 said that they felt that a pharmacy</p> <p>20 should not receive more than this</p> <p>21 amount, and that's what the president</p> <p>22 worked with. He really took it to the</p> <p>23 extreme and was very concerned about it</p> <p>24 and cut off a lot of customers as a</p>	<p style="text-align: right;">Page 48</p> <p>1 responsibility for them, I don't really</p> <p>2 know what they were doing.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. Well, we know they didn't have a</p> <p>5 robust SOM program, right?</p> <p>6 MS. KOSKI: Object to form.</p> <p>7 THE WITNESS: Well, that's</p> <p>8 opinion-based, to be honest.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. And certainly opinion-based four</p> <p>11 years ago, right?</p> <p>12 MS. KOSKI: Object to form.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Nearer in time than today, right?</p> <p>16 A. I'm sorry?</p> <p>17 Q. Nearer in time to the events than</p> <p>18 today, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And a program that certainly</p> <p>21 necessitated immediate action, fair?</p> <p>22 MS. KOSKI: Object to form.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. That's what you wrote at a point</p>
<p style="text-align: right;">Page 47</p> <p>1 result.</p> <p>2 I think, unfortunately for Anda,</p> <p>3 in doing that, the number was a -- kind</p> <p>4 of an ad hoc number thrown out by DEA,</p> <p>5 again, when the SOM program was</p> <p>6 developing. So they just cut based on</p> <p>7 that number only, and they didn't look</p> <p>8 at the customer's business and whether</p> <p>9 that business actually required more</p> <p>10 volume.</p> <p>11 So, you know, they took a very,</p> <p>12 very aggressive approach and were very</p> <p>13 concerned about the information the DEA</p> <p>14 had shared.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Right.</p> <p>17 We can agree, certainly, that</p> <p>18 prior to the point of time of that sit-down with</p> <p>19 the DEA, Anda had not been looking at customers</p> <p>20 in a manner that was looking for suspicious</p> <p>21 orders, correct?</p> <p>22 MS. KOSKI: Object to form.</p> <p>23 THE WITNESS: I can't really say</p> <p>24 that, again, because I didn't have</p>	<p style="text-align: right;">Page 49</p> <p>1 in time nearer to today?</p> <p>2 A. Yes, that's what I wrote.</p> <p>3 Q. And you said some other things</p> <p>4 that you implemented with them -- and this is</p> <p>5 back in at least before 2009, "Prior to my</p> <p>6 leaving," you said you were "instrumental in</p> <p>7 convincing Watson to start looking at drug</p> <p>8 combinations, i.e., Holy Trinity and to begin</p> <p>9 customer visits for the purpose of SOM which I</p> <p>10 believe they now contract out to a third party.</p> <p>11 Did I read that correctly?</p> <p>12 A. Yes.</p> <p>13 Q. So during the time that you were</p> <p>14 at Watson and I guess you were helping them to</p> <p>15 further reshape their SOM program, is this</p> <p>16 Watson/Anda or is this Watson?</p> <p>17 A. This is Watson.</p> <p>18 Q. So on the manufacturer side --</p> <p>19 when we said Watson we're thinking manufacturer</p> <p>20 and when we're thinking Anda you're thinking</p> <p>21 more distributor; is that fair?</p> <p>22 A. Yes.</p> <p>23 Q. With regard to Watson as a</p> <p>24 manufacturer back in 2009 they were starting to</p>

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<p style="text-align: right;">Page 50</p> <p>1 implement customer visits but they were doing 2 with a third party? 3 A. They were -- I have that, I 4 believe, they now contract out to a third party. 5 I don't know if they implemented that after I 6 left. 7 Q. Okay. 8 A. Watson was very -- very proactive 9 and it wasn't just based on my input, it was 10 really a team effort and customer service was 11 also very proactive in -- we worked together to 12 kind of go above and beyond. There was no 13 requirement for Holy Trinity -- you know, to 14 look at Holy Trinity. There was no requirement 15 for -- there were certain products that weren't 16 controlled yet, but that we had heard there was 17 an abuse potential that we added to the system, 18 so a lot of good things that were added above 19 and beyond. 20 Q. Well, there is a requirement to 21 maintain effective controls against diversion, 22 true? 23 A. Yes, within -- within the 24 regulations which apply. When they're talking</p>	<p style="text-align: right;">Page 52</p> <p>1 correct? 2 A. Again, not sure if that actually 3 came to fruition or not. 4 Q. What you noted here -- 5 A. It was something we talked about. 6 Q. -- "prior to my leaving, I was 7 instrumental" -- your words, correct, 8 "instrumental"? 9 A. Mm-hmm. 10 Q. -- "in convincing Watson to start 11 looking at drug combinations, i.e., Holy 12 Trinity, and to begin customer visits for the 13 purpose of SOM, which I believe they now 14 contract out to a third party." 15 Did I read that correctly? 16 A. To start looking at beginning 17 customer visits, to start looking at. There's a 18 difference between implementing versus start 19 looking at. So doing research as to whether or 20 not they wanted to implement customer visits. 21 There's a lot involved in implementing that. 22 Q. The jury has your words, but the 23 words you wrote was, "I was instrumental in 24 convincing Watson" -- and you list two things,</p>
<p style="text-align: right;">Page 51</p> <p>1 more about effective controls against diversion, 2 you know, reporting suspicious orders, it's 3 not -- it's not all-encompassing. It includes a 4 security provision, accountability, 5 recordkeeping. 6 Q. Let's just separate the two so 7 we're not kind of fusing them together. 8 The statutory obligation for 9 manufacturers and distributors who are 10 registrants, thank you for that clarification, 11 is to maintain effective controls against 12 diversion, fair? 13 A. Is to make sure that you are 14 doing everything that you can to prevent your 15 product from being diverted into a list of 16 channels. 17 Q. And one of the things that you 18 implemented or helped Watson implement during 19 your time there was expanding their 20 antidiversion controls to include looking at 21 drug combinations like Holy Trinity. That was 22 one thing, correct? 23 A. Yes. 24 Q. To begin customer visits,</p>	<p style="text-align: right;">Page 53</p> <p>1 right? 2 MS. VANNI: Object to form. 3 THE WITNESS: Mm-hmm. 4 BY MR. BUCHANAN: 5 Q. "I was instrumental in convincing 6 Watson," and then you say the first one, "to 7 start looking at drug combinations," that is, 8 Holy Trinity. That was the first item, correct? 9 A. Yes. 10 Q. Holy Trinity is what? 11 A. It's a combination of 12 hydrocodone, carisoprodol and alprazolam. 13 Q. In your field, and certainly in 14 DEA compliance, you understood that the Holy 15 Trinity, those three drugs, were often abused in 16 combination, fair? 17 A. That's what I was told at 18 conferences, yes. 19 Q. And so as far back as at this 20 point in time, sometime prior to 2009, when you 21 were at Watson, you were instrumental in 22 convincing Watson to start looking at that drug 23 combination as a combination of abuse, fair? 24 A. Yes.</p>



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<p style="text-align: right;">Page 54</p> <p>1 Q. Okay. And then you said there</p> <p>2 was a second thing you were instrumental in,</p> <p>3 correct?</p> <p>4 A. Mm-hmm.</p> <p>5 Q. You were instrumental in</p> <p>6 "convincing Watson to begin customer visits for</p> <p>7 the purpose of SOM, which I believe they now</p> <p>8 contract out to a third party."</p> <p>9 Did I read that correctly?</p> <p>10 A. Yes.</p> <p>11 Q. All right. So that takes us</p> <p>12 through your time at Watson. Actually, let's go</p> <p>13 up the page a little bit.</p> <p>14 Characterizing some other things</p> <p>15 that Watson was doing on the manufacturing side,</p> <p>16 you list the way in which they handled SOM</p> <p>17 during the seven years you were there.</p> <p>18 Do you see that?</p> <p>19 A. Mm-hmm.</p> <p>20 Q. We can start at the beginning.</p> <p>21 "Conducted audits as noted above, Watson already</p> <p>22 utilized NTIS, but based on the requirements of</p> <p>23 several states, added the process for collecting</p> <p>24 customer state license information."</p>	<p style="text-align: right;">Page 56</p> <p>1 doing and had implemented was they were doing</p> <p>2 license checks in connection with each order,</p> <p>3 correct?</p> <p>4 A. Mm-hmm, yes.</p> <p>5 Q. It was something that they were</p> <p>6 already doing before you got there, right?</p> <p>7 A. Yes.</p> <p>8 Q. So if you were there from 2002 to</p> <p>9 2009, they had already implemented as part of</p> <p>10 their order flow a license check every time</p> <p>11 somebody placed an order to ensure that the</p> <p>12 customer was permitted to receive the product,</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. All right. That was actually</p> <p>16 something you implemented for Ciba-Geigy and</p> <p>17 Novartis, right?</p> <p>18 A. Yes.</p> <p>19 Q. If we go up on the page --</p> <p>20 A. Mm-hmm.</p> <p>21 Q. -- it says "responsible for</p> <p>22 conducting internal audits of customer service."</p> <p>23 You talk about "to assure</p> <p>24 customer licensing was obtained and verified."</p>
<p style="text-align: right;">Page 55</p> <p>1 NTIS, is that a way of</p> <p>2 determining whether somebody is, in fact, a</p> <p>3 registrant who is a customer of yours?</p> <p>4 A. It's National Technical</p> <p>5 Information systems or Service, and it's a</p> <p>6 government -- government-run tool that can be</p> <p>7 purchased, and it helps you -- your licenses</p> <p>8 typically expire yearly, but in this particular</p> <p>9 case, if you have this tool, you can look at</p> <p>10 licenses in between that yearly expiration to</p> <p>11 determine -- catch licenses that might have been</p> <p>12 suspended.</p> <p>13 Q. You would agree that it's an</p> <p>14 important thing to make sure -- in a closed</p> <p>15 system of controlled substance drug distribution</p> <p>16 to make sure if you are a manufacturer</p> <p>17 distributor that you are only selling drug to</p> <p>18 people who are --</p> <p>19 MS. LEIBELL: Object to form.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. -- permitted or licensed to</p> <p>22 receive drug?</p> <p>23 A. Yes.</p> <p>24 Q. So one of the things Watson was</p>	<p style="text-align: right;">Page 57</p> <p>1 You see the first sentence of the</p> <p>2 paragraph?</p> <p>3 A. Yes.</p> <p>4 Q. The section sentence says</p> <p>5 "modified process to include the use of the NTIS</p> <p>6 tape to assure license checks occurred at each</p> <p>7 order rather than depending on customers to</p> <p>8 provide new license at expiry."</p> <p>9 And then you talk about increased</p> <p>10 awareness and how you did the monthly monitoring</p> <p>11 reports and various submissions around that,</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. But all the way back prior to</p> <p>15 your time at Watson, even implementing</p> <p>16 transaction-level order checks was something</p> <p>17 that you thought was important and you</p> <p>18 implemented, correct?</p> <p>19 MS. VANNI: Object to the form.</p> <p>20 THE WITNESS: Yes, certain --</p> <p>21 certain types of checks, yes.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. Am I correct, ma'am, that under</p> <p>24 the Controlled Substance Act, it's supposed to</p>

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<p style="text-align: right;">Page 58</p> <p>1 be a closed system of manufacturer, 2 distribution, prescription, et cetera? 3 A. Yes, that's correct. 4 Q. And so if there's any leak in 5 that system, in that -- in all the players in 6 that system, then there's diversion risk, fair? 7 MS. VANNI: Object to form. 8 THE WITNESS: Then there is a DEA 9 violation. 10 BY MR. BUCHANAN: 11 Q. And diversion risk? 12 MS. VANNI: Object to form. 13 THE WITNESS: Potentially. 14 BY MR. BUCHANAN: 15 Q. I mean, you understand that as 16 somebody in the -- in the industry; if drug is 17 being sold to somebody not permitted to get it, 18 by law, it's not a closed system, right? 19 A. Yes. 20 Q. And when you apply for a 21 registration, when a manufacturer distributor 22 applies for a registration, they apply for that 23 registration making the representation they're 24 going to do everything they can to maintain a</p>	<p style="text-align: right;">Page 60</p> <p>1 Do you see that? 2 A. Yes. 3 Q. That was something you were 4 doing -- that was you who was doing that? 5 A. Working with customer service. 6 Q. And to run shipping history for 7 customers of concern? 8 A. Mm-hmm. 9 Q. Okay. And then you also had -- 10 you. Bad word. Withdrawn. 11 Watson also had a suspicious 12 order monitoring system that included a 13 multiplier, and then you would adjust the 14 multiplier on a customer-to-customer basis, 15 correct? 16 A. I don't believe we could adjust 17 it at a customer level. I think it was adjusted 18 overall for the class of trade. 19 Q. So you had class-of-trade 20 adjustments at Watson? 21 A. I believe it was by class of 22 trade. I'm not positive. 23 Q. And class of trade, meaning 24 Watson could have clients who were distributors,</p>
<p style="text-align: right;">Page 59</p> <p>1 closed system, right? 2 MS. VANNI: Object to form. 3 THE WITNESS: Yes. 4 BY MR. BUCHANAN: 5 Q. And I mean, that's been true -- 6 and that's not a change in the regulations, 7 that's been true for as long as you've been 8 involved with controlled substances, correct? 9 MS. VANNI: Object to form. 10 THE WITNESS: Yes. 11 BY MR. BUCHANAN: 12 Q. So let's go back, if we could, to 13 Watson. I realize I'm hopping around. Sorry 14 about that. 15 We'll go back to Watson. 16 And then you note that during 17 your time at Watson, Watson was running shipping 18 history for certain customers of concern, right? 19 A. Just trying to see where your -- 20 Q. Oh, I'm sorry, I realize I've 21 been hopping around. 22 "As part of the internal audits, 23 began to run shipping history for certain 24 customers of concern."</p>	<p style="text-align: right;">Page 61</p> <p>1 correct? 2 A. Wholesalers would be one class of 3 trade. It's basically, for the most part, DEA 4 license type. 5 Q. Okay. And can you identify the 6 various classes of trade? 7 A. Not all, but a wholesaler would 8 be one. A chain drug store might be another. A 9 physician, not necessarily for Watson, but if 10 we -- if you were to distribute to physicians, 11 that would be a class of trade, clinic or 12 hospital, long-term care. 13 Q. And how about -- I'm sorry. 14 A. Long-term care. There's quite a 15 few. 16 Q. Okay. And how about just 17 independent pharmacy, is that a separate class 18 of trade? 19 A. Yes. 20 Q. And so during your time at 21 Watson, you were responsible for the multipliers 22 for the various class of trades, right? 23 A. Yes. 24 Q. And when you say multiplier, what</p>

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<p style="text-align: right;">Page 62</p> <p>1 does that mean?</p> <p>2 A. It's really a part of the SOM</p> <p>3 system, the percentage of orders that you would</p> <p>4 look at. So, for example, when you create the</p> <p>5 system, you want to make sure that you're</p> <p>6 catching orders that are legitimately of concern</p> <p>7 from a quantity perspective, but you also want</p> <p>8 to make sure it's not catching every single</p> <p>9 order.</p> <p>10 You know, you have to know --</p> <p>11 it's almost like setting a threshold really.</p> <p>12 You have to know what -- where you want to cut</p> <p>13 that off. So when you first set up your system,</p> <p>14 it could stop everything if you don't have a</p> <p>15 multiplier that would dial down to where you</p> <p>16 think is reasonable orders that you would want</p> <p>17 to investigate further.</p> <p>18 Q. So a system, essentially, that</p> <p>19 would identify orders that are red flags to be</p> <p>20 further investigated; would that be fair?</p> <p>21 A. Well, that's the SOM system, yes.</p> <p>22 Q. Okay. And the way --</p> <p>23 A. This is one piece of -- I'm</p> <p>24 sorry -- this is one piece of the SOM system.</p>	<p style="text-align: right;">Page 64</p> <p>1 A. Mm-hmm.</p> <p>2 Q. And what were the circumstances</p> <p>3 of your -- you weren't brought in to take</p> <p>4 responsibility for the SOM system for Qualitest,</p> <p>5 right?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: It was part of the</p> <p>8 regulations, so ultimately I would have</p> <p>9 responsibility for it. There's nothing</p> <p>10 that requires the things that I have</p> <p>11 responsibility for to report in to me,</p> <p>12 just more that I'm overseeing them.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. When you arrived at Qualitest,</p> <p>15 SOM was being handled by a different group,</p> <p>16 right?</p> <p>17 A. Correct.</p> <p>18 Q. And that was true for several</p> <p>19 years, right?</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: It became more of a</p> <p>22 partnership.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. In 2013, I think, after the</p>
<p style="text-align: right;">Page 63</p> <p>1 Q. Got you. So the multiplier was a</p> <p>2 component of an order monitoring system, fair?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And the multiplier was</p> <p>5 used to set effectively where an order would get</p> <p>6 flagged as an order to be investigated further,</p> <p>7 fair?</p> <p>8 A. For Watson, yes.</p> <p>9 Q. Yes.</p> <p>10 And this was happening on the</p> <p>11 Watson, if you will, manufacturing side during</p> <p>12 your entire tenure there?</p> <p>13 A. Yes.</p> <p>14 Q. Okay.</p> <p>15 A. It was part of Watson's system.</p> <p>16 It may not be part of other systems, depending</p> <p>17 on how it's developed.</p> <p>18 Q. Okay, yeah, and I was referring</p> <p>19 to, you know, Watson had the system that you've</p> <p>20 described in your testimony and in this writing</p> <p>21 during the entire time you were there?</p> <p>22 A. Right.</p> <p>23 Q. Okay. Then you talk about your</p> <p>24 time at Qualitest, right?</p>	<p style="text-align: right;">Page 65</p> <p>1 meeting with the DEA, you were able to bring</p> <p>2 that under your umbrella more directly, fair?</p> <p>3 MS. VANNI: Object to form.</p> <p>4 THE WITNESS: Not sure exactly</p> <p>5 when it occurred, but I think it was</p> <p>6 before then, I believe.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. When you actually had</p> <p>9 responsibility for it?</p> <p>10 A. Yes, I believe so.</p> <p>11 Q. Let's just get some -- some dates</p> <p>12 kind of on a visual timeline, if you will.</p> <p>13 You joined Qualitest in the</p> <p>14 summer of 2011?</p> <p>15 A. Yes.</p> <p>16 Q. You had some interactions with</p> <p>17 DEA on various matters through the years, but</p> <p>18 then you have the meeting with the DEA in March</p> <p>19 of 2013, right?</p> <p>20 MS. VANNI: Objection.</p> <p>21 THE WITNESS: There were several</p> <p>22 meetings with DEA, I believe, on</p> <p>23 different topics, but --</p> <p>24 BY MR. BUCHANAN:</p>

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<p style="text-align: right;">Page 66</p> <p>1 Q. There was one specific meeting of 2 note where they handed you a binder and similar 3 to the meeting -- 4 A. The distributor initiative. 5 Q. Similar to a meeting that you had 6 had with Anda and Watson several years before? 7 MS. KOSKI: Object to form. 8 MS. LEIBELL: Object to form. 9 MS. VANNI: Object to form. 10 THE WITNESS: Yes, the 11 distributor initiative. 12 BY MR. BUCHANAN: 13 Q. What you're calling the 14 distributor initiative was a sit-down -- in the 15 industry at that in time, you knew that DEA was 16 meeting with people, right? 17 A. Yes. 18 Q. In fact, you knew that firsthand 19 because you had gotten called in to talk to the 20 DEA for Anda and Watson, right? 21 MS. KOSKI: Object to form. 22 THE WITNESS: Yes. 23 BY MR. BUCHANAN: 24 Q. And you knew what that meeting</p>	<p style="text-align: right;">Page 68</p> <p>1 Q. At least in that form, right? 2 A. Correct. 3 Q. You had certain information they 4 didn't have, right? 5 MS. VANNI: Object to form. 6 THE WITNESS: Yes. 7 BY MR. BUCHANAN: 8 Q. I mean, the manufacturer, of 9 course, has business relationships with its 10 various distributors and wholesalers, and under 11 those agreements, there are often chargeback 12 agreements, correct? 13 MS. VANNI: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BUCHANAN: 16 Q. And those chargeback agreements 17 yield an exchange of information that provides 18 visibility to the manufacturer of the secondary 19 customers of the distributor, correct? 20 MS. VANNI: Object to form. 21 THE WITNESS: Sometimes. 22 Chargebacks are not a very -- not a very 23 dependable tool for multiple reasons. 24 BY MR. BUCHANAN:</p>
<p style="text-align: right;">Page 67</p> <p>1 was about, right? 2 A. Uh-huh. Yes. 3 Q. They were basically telling 4 people, manufacturers, distributors, you've got 5 to have effective controls against diversion, 6 and they got specific about some of the things 7 that had to be done, right? 8 MS. VANNI: Object to form. 9 THE WITNESS: It was more of a 10 review. It was more that I think they 11 had -- they realized they had a tool 12 that could be helpful to distributors in 13 the ARCOS data, and if they compiled it 14 in that way and showed it to us, it 15 would be helpful to us. 16 We did not have the capability to 17 see down to -- down beyond the customer 18 that we shipped to, and so that was 19 really, I think, the driver for their 20 meetings, the distributor initiatives. 21 BY MR. BUCHANAN: 22 Q. Right, they had certain data that 23 you didn't have full visibility to? 24 A. Correct.</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. Well, they're certainly good 2 enough for people to exchange a lot of money 3 back and forth with, right? 4 MS. VANNI: Objection. 5 THE WITNESS: I don't know. I 6 don't really know a lot about chargeback 7 data. 8 BY MR. BUCHANAN: 9 Q. Well, you do know that 10 chargebacks are a means for which manufacturers 11 and distributors exchange big checks, right? 12 MS. VANNI: Objection. 13 THE WITNESS: I don't know. I 14 know that it's a rebate type of program, 15 but other than that, I don't know 16 whether it's big or whether it's small. 17 I don't know a lot about the financial 18 aspects of it. 19 BY MR. BUCHANAN: 20 Q. Right. It's a system that's used 21 between manufacturers and distributors whereby 22 if a distributor ends up having to sell its 23 product to its end user pharmacies and customers 24 for less or at some type of discount relative to</p>

18 (Pages 66 to 69)

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<p style="text-align: right;">Page 70</p> <p>1 what it paid for it, it can get money back from 2 the manufacturer, fair? 3 MS. VANNI: Objection. 4 THE WITNESS: From what I know, 5 yes. 6 BY MR. BUCHANAN: 7 Q. That's a decent thumbnail sketch 8 of what we're talking about with the business 9 purpose -- primary business purpose of 10 chargeback data, correct? 11 A. Yes. 12 Q. And as part of that, the 13 distributor has got to come forward with its 14 sales information to its end user customers, 15 correct? 16 A. Yes. 17 MS. VANNI: Objection. 18 THE WITNESS: Yes. 19 BY MR. BUCHANAN: 20 Q. And so the manufacturers then, as 21 part of that reconciliation process, given end 22 user customer information as part of the 23 chargeback agreements, correct? 24 MS. VANNI: Objection.</p>	<p style="text-align: right;">Page 72</p> <p>1 data as part of its suspicious order monitoring 2 tools, correct? 3 MS. VANNI: Objection. 4 THE WITNESS: The company 5 reviewed the potential of including 6 chargeback data. At the time that I had 7 left, we had not implemented it. I 8 don't know if it was implemented after. 9 BY MR. BUCHANAN: 10 Q. Okay. We'll talk about that in a 11 little more detail. 12 A. Let me be clear, though. There 13 is no -- there's no DEA regulation that requires 14 a company to include chargeback data in their 15 SOM program. 16 Q. Qualitest at the point in time 17 when they implemented this -- and I guess 18 there's some debate between you and I at the 19 moment, and we'll just have to work through this 20 during the day, as to whether Qualitest ever 21 actually looked at chargeback data and used it 22 as part of its suspicious order monitoring 23 program. 24 Is it your contention, as least</p>
<p style="text-align: right;">Page 71</p> <p>1 THE WITNESS: Yes, on some 2 customers. 3 BY MR. BUCHANAN: 4 Q. Right, and some customers -- 5 A. Some don't participate. 6 Q. Right. Your larger wholesalers 7 and distributors have chargeback agreements with 8 the manufacturers, correct? 9 MS. VANNI: Objection. 10 THE WITNESS: I don't know. 11 BY MR. BUCHANAN: 12 Q. Okay. Well, during your time at 13 Qualitest, you did have access to chargeback 14 data, correct? 15 A. I looked at the data. I met with 16 financial individuals, and the data was not 17 helpful at that time. 18 Q. Okay. We'll highlight that 19 answer and we'll circle back at some point 20 during the day on that. 21 A. Yes. 22 Q. You would agree that during the 23 time that you were at Qualitest, the company 24 implemented a system to incorporate chargeback</p>	<p style="text-align: right;">Page 73</p> <p>1 as you are sitting here now, you don't recall 2 Qualitest doing that for its customers? 3 MS. VANNI: Object to form. 4 THE WITNESS: When I was there, 5 we did not. 6 BY MR. BUCHANAN: 7 Q. Okay. Looking now to your 8 description -- it's 1146.3, those are numbers in 9 the top right corner, I'll reference them from 10 time to time, but it's Exhibit 2 for the 11 record -- this says "Upon arrival at Qualitest, 12 I did not have responsibility for SOMs." 13 Was there a particular DEA issue 14 that you were brought in to deal with in 15 Alabama? 16 MS. VANNI: Object to form. 17 THE WITNESS: I was brought in to 18 basically implement a DEA program 19 overall. Wasn't SOM specific. 20 BY MR. BUCHANAN: 21 Q. Who was the DEA compliance person 22 that you replaced? 23 A. John Schultz. 24 Q. Okay. If I understand correctly,</p>



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<p style="text-align: right;">Page 74</p> <p>1 historic files show that Qualitest had separate</p> <p>2 incidents with DEA which caused a bit of a stir,</p> <p>3 fair?</p> <p>4 MS. VANNI: Objection.</p> <p>5 THE WITNESS: Yes.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. What were those?</p> <p>8 A. Well, we had multiple</p> <p>9 interactions with DEA. Are you referring to</p> <p>10 prior to my coming?</p> <p>11 Q. Prior to your coming, yes, the</p> <p>12 issues that you were aware of that created a bit</p> <p>13 of a stir.</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: I was told that</p> <p>16 there was a theft, and that that's why</p> <p>17 Mr. Schultz was being let go.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Okay. And was that in the</p> <p>20 Charlottesville facility or in the Huntsville</p> <p>21 facility?</p> <p>22 A. Huntsville.</p> <p>23 Q. Okay. And what was the other</p> <p>24 incident?</p>	<p style="text-align: right;">Page 76</p> <p>1 where you're referring to?</p> <p>2 MR. BUCHANAN: It's in this and</p> <p>3 outside of this.</p> <p>4 THE WITNESS: License checks, I</p> <p>5 was not concerned. I know they were</p> <p>6 checking the licenses.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. On an order-by-order basis?</p> <p>9 A. I don't believe it was on an</p> <p>10 order-by-order basis. DEA required at the time</p> <p>11 and still requires really that you check the</p> <p>12 license when you get a copy of the customer's</p> <p>13 license, and that license is good for a year.</p> <p>14 There's no DEA requirement, in other words, to</p> <p>15 purchase NTIS data.</p> <p>16 Q. Okay. Fair enough. But all the</p> <p>17 way back in the '90s, I mean, when you were at</p> <p>18 Ciba-Geigy, I mean, Ciba-Geigy had an NTIS data</p> <p>19 stream that was checking orders as they were</p> <p>20 placed, correct?</p> <p>21 A. It was available, yes, yes.</p> <p>22 Q. And that's how they were doing it</p> <p>23 back in the '90s?</p> <p>24 MS. VANNI: Object to form.</p>
<p style="text-align: right;">Page 75</p> <p>1 A. That's the -- that's the only one</p> <p>2 I'm aware of prior to my coming.</p> <p>3 Q. Okay. Are you aware of incidents</p> <p>4 where the company was shipping products to</p> <p>5 people who didn't have DEA licenses?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: No, I'm not.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. Not during your time nor before</p> <p>10 your time, you're not aware of that?</p> <p>11 A. No, I'm not.</p> <p>12 Q. Okay. And then you describe in</p> <p>13 the middle, that you were "very concerned with</p> <p>14 the status of the SOM program."</p> <p>15 Do you recall that?</p> <p>16 A. Yes.</p> <p>17 Q. Not just writing it, but you</p> <p>18 recall that?</p> <p>19 A. Yes.</p> <p>20 Q. You recall being very concerned</p> <p>21 about where Qualitest was with regard to license</p> <p>22 checks, for example?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 Counsel, can you point me to</p>	<p style="text-align: right;">Page 77</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Okay. And that's how Watson was</p> <p>4 doing it before you -- before you got to Watson?</p> <p>5 A. Correct. Yes.</p> <p>6 Q. And before you got to Qualitest,</p> <p>7 it would be fair that you had to add the NTIS</p> <p>8 and state license checks to the system, right?</p> <p>9 A. I didn't have to. It was an</p> <p>10 upgrade that I wanted to make.</p> <p>11 Q. Okay. What you stated here was</p> <p>12 you were very concerned with the status of the</p> <p>13 program and began to work with sales, customer</p> <p>14 service and IT to make improvements and with</p> <p>15 your management to raise your concerns.</p> <p>16 Would it be fair that you raised</p> <p>17 concerns?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: About the SOM</p> <p>20 program?</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Yes.</p> <p>23 A. The concerns I had with the SOM</p> <p>24 program was that it was being handled by sales</p>

20 (Pages 74 to 77)

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<p style="text-align: right;">Page 78</p> <p>1 and they were reviewing what they needed to. My</p> <p>2 concern was the perception that sales was the</p> <p>3 one handling it, and how that would be perceived</p> <p>4 by others.</p> <p>5 Q. Right, because, I mean, you know</p> <p>6 there's -- the salespeople are about selling,</p> <p>7 right?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: That's what people</p> <p>10 would perceive, yes.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. I mean, that's not an</p> <p>13 unreasonable perception, right?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: It is a perception</p> <p>16 that's out there --</p> <p>17 BY MR. BUCHANAN</p> <p>18 Q. Right.</p> <p>19 A. And regardless of how -- you</p> <p>20 know, salespeople have integrity, too, believe</p> <p>21 it or not.</p> <p>22 Q. Do you recall getting some</p> <p>23 pushback from the sales side of Qualitest as you</p> <p>24 started to implement and explore various SOMs</p>	<p style="text-align: right;">Page 80</p> <p>1 off, they were on board anytime that I</p> <p>2 interacted with them.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. Right.</p> <p>5 So once you showed them diligence</p> <p>6 that you had done -- or investigation that had</p> <p>7 been done, a review of data that had been</p> <p>8 conducted, people were willing to accept the</p> <p>9 conclusion, fair?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. But you've got to do the</p> <p>12 diligence, you've got to do the digging, you had</p> <p>13 to make the case?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: Yes. We're not</p> <p>16 going to, you know, stop shipping to a</p> <p>17 customer without justification, sure.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. So it's really hard to develop</p> <p>20 that justification if you're not doing due</p> <p>21 diligence on customers, correct?</p> <p>22 MS. VANNI: Object to form.</p> <p>23 THE WITNESS: No, because sales</p> <p>24 was contacting me. If they had a</p>
<p style="text-align: right;">Page 79</p> <p>1 initiatives --</p> <p>2 MS. VANNI: Objection.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. -- after your meeting with the</p> <p>5 DEA?</p> <p>6 A. Questions from them? I think</p> <p>7 that the education, we needed to educate a</p> <p>8 little bit more. As far as how DEA looked at</p> <p>9 the program -- not looked at the program, but</p> <p>10 how they -- how the regulation had changed over</p> <p>11 the years and how the perception of the</p> <p>12 regulation and the things that DEA would like to</p> <p>13 see changed over the years.</p> <p>14 Q. My question was simply whether</p> <p>15 you got some -- some pushback from sales as you</p> <p>16 were starting to implement, restrict and propose</p> <p>17 terminating certain customers.</p> <p>18 Do you recall that?</p> <p>19 MS. VANNI: Objection.</p> <p>20 THE WITNESS: I think you will</p> <p>21 always get pushback from sales at any</p> <p>22 company when you're cutting off a</p> <p>23 customer, but when we gave information</p> <p>24 as to why that customer needed to be cut</p>	<p style="text-align: right;">Page 81</p> <p>1 concern about a particular customer,</p> <p>2 they were really, really good with</p> <p>3 bringing things forward and asking</p> <p>4 questions, and so we were working</p> <p>5 together on it.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. Okay. It says here in early 2013</p> <p>8 you received a program -- you received approval</p> <p>9 to move the SOM program into DEA compliance.</p> <p>10 Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Does that help refresh</p> <p>13 your recollection as to when that came under</p> <p>14 your umbrella?</p> <p>15 A. Yes, thank you.</p> <p>16 Q. Okay. So prior to that point in</p> <p>17 time, it was a sales function, right?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. Sales, customer service? Excuse</p> <p>21 me.</p> <p>22 A. It was under the sales</p> <p>23 department, managed by the sales department with</p> <p>24 input.</p>

21 (Pages 78 to 81)



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<p style="text-align: right;">Page 82</p> <p>1 Q. Right, so --</p> <p>2 A. With compliance input.</p> <p>3 Q. And so in 2013, you brought it</p> <p>4 into the DEA compliance group.</p> <p>5 Were you the head of DEA</p> <p>6 compliance at that point in time?</p> <p>7 A. Yes.</p> <p>8 Q. And that was the title you held</p> <p>9 until you left?</p> <p>10 A. Yes.</p> <p>11 Q. Why did you leave?</p> <p>12 A. A better position, promotion. I</p> <p>13 went to H.D. Smith as the VP.</p> <p>14 Q. Okay. There was a -- you left --</p> <p>15 let's just look at Exhibit 2. Exhibit 2 is</p> <p>16 dated October 15th, 2014.</p> <p>17 Two weeks before this, you got</p> <p>18 that letter from the U.S. Attorney in Alabama</p> <p>19 about egregious violations?</p> <p>20 A. Prior to me leaving?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. Yeah. Do you recall that?</p> <p>24 A. We had -- we had inspections by</p>	<p style="text-align: right;">Page 84</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. I'm passing you, Ms. Norton, a</p> <p>3 copy of Exhibit 3 to your deposition. This is a</p> <p>4 letter from the U.S. Attorney, U.S. Department</p> <p>5 of Justice, Joyce Vance, United States Attorney,</p> <p>6 I guess for the Northern District of Alabama,</p> <p>7 it's dated September 30, 2014, 1060.2. If you</p> <p>8 could pull it up, please.</p> <p>9 And do you see before -- I guess</p> <p>10 you read the content of it, ma'am, do you see</p> <p>11 you're on this exchange?</p> <p>12 A. Yes, I do.</p> <p>13 Q. Okay. You are the point of</p> <p>14 contact from the Department of Justice on this</p> <p>15 particular correspondence from the U.S.</p> <p>16 Attorney's Office?</p> <p>17 A. Yes.</p> <p>18 Q. It says "Ms. Hernandez, please</p> <p>19 find attached the Notice of Intent to Seek Civil</p> <p>20 Penalties."</p> <p>21 Do you see that on the cover, the</p> <p>22 cover e-mail?</p> <p>23 A. Yes.</p> <p>24 Q. And this is September 30, 2014,</p>
<p style="text-align: right;">Page 83</p> <p>1 DEA throughout my time at Qualitest. I don't</p> <p>2 know which -- what instance you are referring</p> <p>3 to, but we did have occasions where we had</p> <p>4 violation letters.</p> <p>5 Q. Okay. And do you recall -- do</p> <p>6 you recall getting a letter not from the DEA,</p> <p>7 but from the U.S. Attorney directed to you,</p> <p>8 telling you that there were egregious violations</p> <p>9 and you had a week to sit down with them to talk</p> <p>10 about your fine?</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: I don't recall</p> <p>13 that.</p> <p>14 THE VIDEOGRAPHER: Counsel, could</p> <p>15 we go off the record just momentarily?</p> <p>16 MR. BUCHANAN: Yeah.</p> <p>17 THE VIDEOGRAPHER: Going off the</p> <p>18 record. The time is now 9:53 a.m.</p> <p>19 (Brief recess.)</p> <p>20 THE VIDEOGRAPHER: Back on the</p> <p>21 record. The time is 9:55 a.m.</p> <p>22 (Document marked for</p> <p>23 identification as Par- Norton Deposition</p> <p>24 Exhibit No. 3)</p>	<p style="text-align: right;">Page 85</p> <p>1 it's a couple weeks, it looks like, before you</p> <p>2 are engaging with H.D. Smith in your job search.</p> <p>3 Do you see that?</p> <p>4 A. The date, yes, September 30.</p> <p>5 Q. Is that correct?</p> <p>6 A. Mm-hmm.</p> <p>7 Q. Okay. So you get this letter.</p> <p>8 Please feel free to look at it. It's a</p> <p>9 follow-up letter to a teleconference you had had</p> <p>10 a week earlier on September 22, 2014.</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. It says, "The audit</p> <p>14 revealed alarming deviations of Schedule II and</p> <p>15 Schedule III controlled substances in violation</p> <p>16 of 21 CFR 1304.21, other statutes, you failed to</p> <p>17 account for and properly maintain records of the</p> <p>18 following."</p> <p>19 And then it's got a list of seven</p> <p>20 items there. And, I'm sorry, are you still</p> <p>21 reading?</p> <p>22 A. Yes.</p> <p>23 Q. Okay.</p> <p>24 A. (Witness reviews document.)</p>

22 (Pages 82 to 85)

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<p style="text-align: right;">Page 86</p> <p>1 Q. And can you highlight the items, 2 please. 3 So we see item one, Hydrocodone 4 10, 325 milligrams, that's Hydrocodone 5 10 milligrams, 325 milligrams of acetaminophen, 6 is that what that would be? 7 A. Yes. 8 Q. And so, you know, about roughly 9 1200 bottles unaccounted for, right? 10 A. Mm-hmm. 11 MS. VANNI: Objection to the 12 form. 13 THE WITNESS: Doesn't necessarily 14 mean they were unaccounted for as much 15 as the recordkeeping of them. 16 BY MR. BUCHANAN: 17 Q. Well, it says "GB," and GB is -- 18 A. Generics Bidco. 19 Q. And Generics Bidco was one of the 20 operating entities of Qualitest, correct? 21 A. Yes. 22 Q. One of the registrants with the 23 DEA, correct? 24 A. Yes.</p>	<p style="text-align: right;">Page 88</p> <p>1 correct? 2 A. Mm-hmm. 3 Q. -- "as demonstrated by, among 4 other things, deviations exceeding 9 million 5 tablets." 6 Did I read that correctly? 7 A. Yes. 8 Q. It continues, the follow on 9 paragraph, "GB's recordkeeping violations, in 10 particular, as evidenced by the several-million 11 tablet deviations are" -- and what did they say? 12 A. I'm sorry, where are you looking? 13 Failure to maintain -- 14 Q. "GB's recordkeeping violations, 15 in particular" -- 16 A. Yes. 17 Q. -- "as evidenced by the 18 several-million tablet deviation are," and what 19 do they say? 20 A. -- "egregious and evidence a 21 complete disregard of GB's statutory and 22 regulatory obligations." 23 Q. That's not good. 24 MS. VANNI: Object to form.</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. And there was another registrant 2 with the DEA that also operated under Qualitest, 3 correct? 4 A. Yes. 5 Q. And what was the entity's name? 6 A. Vintage -- Vintage 7 Pharmaceuticals. 8 Q. Right. 9 So what we see here are some 1200 10 bottles of Hydrocodone with 10 milligrams, 1300 11 bottles of hydrocodone seven and a half 12 milligrams, more in different -- in different 13 allocations. 816 bottles of Oxycodone. 14 What's Oxycodone 30 milligrams, 15 ma'am? 16 A. What is it? 17 Q. Yeah. 18 A. I don't -- 19 Q. Is it a generic of Oxycontin? 20 A. Yes. 21 Q. Okay. And then on the next page, 22 it says "The DEA's inspection revealed an 23 overall careless and haphazard recordkeeping 24 practice at GB" -- that's the Qualitest entity,</p>	<p style="text-align: right;">Page 89</p> <p>1 THE WITNESS: The way the DEA 2 and/or the Attorney General words a 3 violation letter is meant to -- meant to 4 be exaggerated for impact. 5 BY MR. BUCHANAN: 6 Q. "Egregious and evidence of a 7 complete disregard of your statutory and 8 regulatory obligation," that's not good, right? 9 MS. VANNI: Object to form. 10 THE WITNESS: It's not -- it's 11 not really descriptive of the situation. 12 BY MR. BUCHANAN: 13 Q. It's certainly not the way a 14 company who is a registrant in a closed system 15 of controlled substance distribution should be 16 contacting itself, right? 17 MS. VANNI: Object to form. 18 THE WITNESS: These letters are 19 also meant to point out violations -- 20 BY MR. BUCHANAN: 21 Q. Can you answer my question? 22 A. I'm sorry, what was the question? 23 Q. Yes. It's not the way in which a 24 manufacturer and registrant of a controlled</p>

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<p style="text-align: right;">Page 90</p> <p>1 substance is supposed to be behaving, correct?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: You don't want any</p> <p>4 violations.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Okay. You certainly don't want</p> <p>7 to engage in egregious and complete disregard of</p> <p>8 your statutory and regulatory obligations, fair?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: And we were not.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Okay. And they said you had a</p> <p>13 week to sit down with them to negotiate your</p> <p>14 fine, right?</p> <p>15 A. Yes.</p> <p>16 Q. And were you part of those</p> <p>17 discussions?</p> <p>18 A. I don't recall.</p> <p>19 Q. Because this is not -- this</p> <p>20 wasn't just the first notice you had from the</p> <p>21 U.S. Attorney, right?</p> <p>22 MS. VANNI: Object to form.</p> <p>23 THE WITNESS: I don't know</p> <p>24 whether we had notices from the Attorney</p>	<p style="text-align: right;">Page 92</p> <p>1 MS. VANNI: Objection.</p> <p>2 THE WITNESS: -- of a DEA</p> <p>3 inspection.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. Right. So you would have had</p> <p>6 interactions with the DEA on this issue before</p> <p>7 you got --</p> <p>8 A. The local office, yes.</p> <p>9 Q. And what fine did Qualitest pay</p> <p>10 in connection with this?</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: I'm not sure.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. Were you a part of those</p> <p>15 discussions?</p> <p>16 A. No, I think I had left already.</p> <p>17 I don't recall.</p> <p>18 Q. Okay. What happened after this</p> <p>19 letter?</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: After any letter --</p> <p>22 and, again, I didn't recall this</p> <p>23 instance offhand -- and I know that the</p> <p>24 quantities that are listed here, the</p>
<p style="text-align: right;">Page 91</p> <p>1 General or violation letters. We did</p> <p>2 have other violation letters, but I</p> <p>3 don't know if the Attorney General was</p> <p>4 involved. Offhand, I don't recall.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Right.</p> <p>7 You had a call with certainly the</p> <p>8 U.S. Attorney a week before this, right?</p> <p>9 A. I don't know for sure.</p> <p>10 Q. First paragraph, last sentence.</p> <p>11 A. Yes.</p> <p>12 Q. Okay. You had a call with the</p> <p>13 U.S. Attorney before this?</p> <p>14 A. So the call would have been -- by</p> <p>15 the looks of it here, the call would have been</p> <p>16 to say do we want this sent by e-mail, do we</p> <p>17 want it sent by mail, et cetera.</p> <p>18 At that point, we probably would</p> <p>19 not know the details of what was included in it</p> <p>20 until it came.</p> <p>21 Q. And you would have had</p> <p>22 interactions with the DEA on this before the</p> <p>23 U.S. Attorney got it, right?</p> <p>24 A. This was a result --</p>	<p style="text-align: right;">Page 93</p> <p>1 issues were surrounding complaint</p> <p>2 samples which get returned to the</p> <p>3 company from customers in various</p> <p>4 conditions and, for example, you might</p> <p>5 receive a liquid in -- that came in in a</p> <p>6 bottle that the bottle is broken and</p> <p>7 there's glass.</p> <p>8 So, I mean, these are not liquid,</p> <p>9 but the complaints that come back from</p> <p>10 customers are not usually in very good</p> <p>11 form, and that's what many of these were</p> <p>12 related to, I believe.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. 9 million pills?</p> <p>15 A. Mm-hmm, yes.</p> <p>16 Q. 9 million pills, you're claiming,</p> <p>17 were cracked bottles?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: No, no, these were</p> <p>20 not bottle -- these, in particular, that</p> <p>21 are listed here are not liquid, but I'm</p> <p>22 giving an example of the condition that</p> <p>23 complaints come back to us.</p> <p>24 BY MR. BUCHANAN:</p>

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<p>1 Q. Okay.</p> <p>2 A. So partial tablets in</p> <p>3 prescription bottles dumped into containers,</p> <p>4 loose, you know, that's what we're dealing with</p> <p>5 from a complaint perspective when those are</p> <p>6 returned to us.</p> <p>7 Q. Okay. Well, specifically on this</p> <p>8 one, were you a part of the investigation around</p> <p>9 this?</p> <p>10 A. I don't recall.</p> <p>11 Q. Who handled the investigation?</p> <p>12 A. I don't know. It was for the</p> <p>13 distribution, Generics Bidco, it would be for</p> <p>14 the distribution center, so I would assume</p> <p>15 someone in distribution, someone who had been</p> <p>16 left on my team. I don't know who else.</p> <p>17 Q. Okay. And so after this</p> <p>18 interaction at least -- and I haven't been able</p> <p>19 to see -- withdrawn.</p> <p>20 After you received this letter,</p> <p>21 we certainly know you're in at least more -- you</p> <p>22 send your resume out, you commence a screening</p> <p>23 process with H.D. Smith to pursue employment</p> <p>24 there, fair?</p>	<p>1 pills? You don't remember that?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: I may have been</p> <p>4 involved in it during my time there, but</p> <p>5 I don't recall any of it. I don't want</p> <p>6 to miscomment on what I did or didn't</p> <p>7 do.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. As part of your separation with</p> <p>10 the company in 2014, did you have interactions</p> <p>11 with management in any way relating to this</p> <p>12 particular event?</p> <p>13 MS. VANNI: Object to form.</p> <p>14 THE WITNESS: I would have</p> <p>15 interactions with management about any</p> <p>16 violation that the company received, so</p> <p>17 I would assume that I did. Again, I</p> <p>18 don't know who or -- I don't recall the</p> <p>19 details of it.</p> <p>20 MR. BUCHANAN: You asked for a</p> <p>21 five-minute break, and I'm good now,</p> <p>22 thanks.</p> <p>23 MS. VANNI: Okay.</p> <p>24 THE VIDEOGRAPHER: Going off the</p>
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<p>1 A. No, not fair. This letter would</p> <p>2 have nothing to do with me leaving the company.</p> <p>3 After the amount of time that I have in a DEA</p> <p>4 compliance role, a violation letter would not</p> <p>5 cause me to leave a company.</p> <p>6 Q. And so -- that's what I'm trying</p> <p>7 to understand.</p> <p>8 We have this letter, you're not</p> <p>9 involved in the investigation around the letter,</p> <p>10 and you're the head of DEA compliance?</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: I don't know if I</p> <p>13 was or not. I just don't recall it.</p> <p>14 It's been a while. I would assume --</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. You had some recollection, ma'am,</p> <p>17 about, you know, getting the ANDA meeting with</p> <p>18 the DEA back in 2008, 2009 -- or the Anda</p> <p>19 meeting, excuse me, in 2008, 2009. You don't</p> <p>20 remember a letter from the U.S. Attorney saying</p> <p>21 we've got to sit down and talk about potentially</p> <p>22 millions of dollars in fines relating to</p> <p>23 egregious, alarming, complete deviations and</p> <p>24 failure to account for more than 9 million</p>	<p>1 record. The time now is 10:06 a m.</p> <p>2 (Brief recess.)</p> <p>3 THE VIDEOGRAPHER: Now going back</p> <p>4 on the record. The time is 10:20 a m.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. As I said, you can set aside that</p> <p>7 last exhibit. You've worked for several</p> <p>8 manufacturers, distributors who are the subject</p> <p>9 of the litigation that brings us here today.</p> <p>10 I'm focusing most of my questions</p> <p>11 during your time on Qualitest, so I've got a</p> <p>12 period of time to do that. Other people may</p> <p>13 have some questions about other points in time.</p> <p>14 A. Yes.</p> <p>15 Q. But you spent some time, I</p> <p>16 assume, meeting with counsel before today to</p> <p>17 kind of run through this?</p> <p>18 A. Yes, I did.</p> <p>19 Q. Okay. Who -- who did you speak</p> <p>20 with by the entity, counsel for?</p> <p>21 A. Counsel for Endo, counsel for</p> <p>22 H.D. Smith and counsel for Watson.</p> <p>23 Q. Okay. Separate counsel for Anda</p> <p>24 or same counsel for both?</p>

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<p style="text-align: right;">Page 98</p> <p>1 A. Briefly for Anda. Briefly for 2 Anda. 3 Q. Okay. And so that was separate 4 counsel for Anda? 5 A. Yes. 6 Q. Okay. And all in one session or 7 in multiple sessions? 8 MS. VANNI: Object to form. 9 THE WITNESS: Multiple. 10 BY MR. BUCHANAN: 11 Q. Okay. When did you first start 12 meeting? 13 A. About a month ago. 14 Q. Okay. And let's talk about kind 15 of in-person meetings first. 16 How many of those did you have? 17 A. I think three with Endo, two with 18 H.D. Smith and one with Watson. 19 Q. Each one of these several hours? 20 MS. VANNI: Object to form. 21 THE WITNESS: Yes. 22 BY MR. BUCHANAN: 23 Q. Okay. You don't currently work 24 for any of the firms whose counsel you met with,</p>	<p style="text-align: right;">Page 100</p> <p>1 A. I do. 2 Q. What is the business of Noramco? 3 A. They are a chemical active 4 ingredient manufacturer. 5 Q. So they make the API? 6 A. Yes. 7 Q. They make APIs that are 8 controlled substances? 9 A. Yes. 10 Q. And which ones do they make? 11 A. They make several. Hydrocodone, 12 oxycodone, Tapentadol. 13 Q. And oxycodone would be the active 14 pharmaceutical ingredient in -- is API an active 15 pharmaceutical ingredient? 16 A. Yes, it is. 17 Q. Okay. So oxycodone is the active 18 pharmaceutical ingredient in Oxycontin? 19 A. Yes. 20 Q. And hydrocodone would be an 21 active pharmaceutical ingredient in products 22 like Vicodin? 23 A. Yes. 24 Q. Okay. And so we'll look at some</p>
<p style="text-align: right;">Page 99</p> <p>1 correct? 2 A. No, I do not. 3 Q. When I said firms, I mean either 4 Endo or H.D. Smith or Watson, correct? 5 A. No, do not. 6 Q. Was your current employer present 7 at any of those meetings? 8 A. Yes. 9 Q. Okay. All of them? 10 A. No. 11 Q. Okay. So that would be an 12 additional meeting or that person attended 13 certain of the meetings? 14 A. Attended certain. 15 Q. Okay. 16 A. And there was an additional 17 meeting with them separately. 18 Q. Okay. And your current employer 19 I see from Exhibit 1 is Noramco? 20 A. Yes, that's correct. 21 Q. Out of [REDACTED]? 22 A. Yes. 23 Q. Do you work in [REDACTED]? 24 [REDACTED]?</p>	<p style="text-align: right;">Page 101</p> <p>1 documents today where they're referenced by 2 hydrocodone APAP or oxycodone. 3 When we see hydrocodone APAP, we 4 can think of that as Vicodin? 5 MS. VANNI: Objection. 6 THE WITNESS: Hydrocodone 7 acetaminophen, yes. 8 BY MR. BUCHANAN: 9 Q. Okay. APAP is an abbreviation in 10 the pharmaceutical industry for acetaminophen, 11 which would retail as Tylenol in its -- if it 12 was just acetaminophen, right? 13 A. Yes. 14 Q. Okay. When you combine 15 essentially Tylenol with the controlled 16 substance hydrocodone, that goes by a brand name 17 of Vicodin, correct? 18 A. Sometimes, yes. 19 Q. Well, Vicodin is hydrocodone and 20 acetaminophen combined, correct? 21 A. Yes. 22 Q. In one tablet? 23 A. Yes. 24 Q. Thank you.</p>



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<p>1 And so the business of Noramco is</p> <p>2 the manufacturer of the -- if you will, the</p> <p>3 active controlled substance that gets ultimately</p> <p>4 put into the tablets that are stamped by</p> <p>5 manufacturers like Qualitest, correct?</p> <p>6 A. Yes, that's correct.</p> <p>7 MS. HERGENROTHER: Objection.</p> <p>8 MR. BUCHANAN: Who is on the line</p> <p>9 and raising that objection for which</p> <p>10 defendant?</p> <p>11 MS. HERGENROTHER: It's Jenny</p> <p>12 Hergenrother for Noramco, Inc.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. All right. So we were running</p> <p>15 through these meetings you had, several hours,</p> <p>16 several meetings, several hours at each meeting</p> <p>17 for several meetings, correct?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: Yes, correct.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. All right. Good. I've got seven</p> <p>22 meetings over the last month?</p> <p>23 A. Approximately.</p> <p>24 Q. Okay. And these are</p>	<p>1 Q. And did it?</p> <p>2 A. Yes.</p> <p>3 Q. What were you shown?</p> <p>4 MS. VANNI: Object to the form.</p> <p>5 I'm going to instruct her not to answer</p> <p>6 as to what she was shown. That's</p> <p>7 clearly work product.</p> <p>8 MR. BUCHANAN: It's actually not.</p> <p>9 I mean, frankly, if you showed her</p> <p>10 anything that refreshed her</p> <p>11 recollection, I'm entitled under Rule</p> <p>12 608 or 611, whatever it is, to copies of</p> <p>13 whatever she was shown, so...</p> <p>14 MS. VANNI: I'm going to instruct</p> <p>15 her not to answer as exactly to what she</p> <p>16 was shown.</p> <p>17 You can ask her how her</p> <p>18 recollection was refreshed or if her</p> <p>19 recollection was refreshed, but -- or if</p> <p>20 she remembers specific documents, but</p> <p>21 she is not going to tell you specific</p> <p>22 documents that she was shown.</p> <p>23 MR. BUCHANAN: If the witness'</p> <p>24 recollection was refreshed by documents</p>
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<p>1 face-to-face, right?</p> <p>2 MS. KOSKI: Object to form.</p> <p>3 THE WITNESS: Most, yes.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. Okay. And then you probably had</p> <p>6 some video conference-type stuff where you</p> <p>7 shared screens. Did that happen, too?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: No.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. No?</p> <p>12 Did you have some teleconferences</p> <p>13 or phone calls?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Did that start before the</p> <p>16 last month?</p> <p>17 A. I'm not positive.</p> <p>18 Q. Okay.</p> <p>19 A. I don't think so.</p> <p>20 Q. Did you review some documents to</p> <p>21 get ready for today?</p> <p>22 A. I was shown some documents, yes.</p> <p>23 Q. Help refresh your memory?</p> <p>24 A. Yes, in some cases, yes.</p>	<p>1 that you showed her, I'm entitled to</p> <p>2 have them so that I can appropriately</p> <p>3 examine her on her refreshed</p> <p>4 recollection. That's the law.</p> <p>5 MS. VANNI: Counsel, this -- you</p> <p>6 know that the documents that she is</p> <p>7 shown by counsel in preparation for</p> <p>8 deposition are protected by</p> <p>9 attorney-client and work product.</p> <p>10 MR. BUCHANAN: We disagree.</p> <p>11 Certainly where it refreshes your</p> <p>12 recollection.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. So please describe the subject</p> <p>15 matter --</p> <p>16 MR. BUCHANAN: You're instructing</p> <p>17 her not to answer, correct?</p> <p>18 MS. VANNI: I am as to what</p> <p>19 specific documents she was shown.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Okay. Let's talk about, then,</p> <p>22 the areas in which you were shown documents.</p> <p>23 You were shown documents</p> <p>24 apparently by counsel for Endo, fair?</p>

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<p style="text-align: right;">Page 106</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And what areas of subject</p> <p>3 matter were those documents?</p> <p>4 A. Oh, gosh. E-mails, inspection</p> <p>5 information.</p> <p>6 Q. Documents you wrote?</p> <p>7 A. Yes.</p> <p>8 Q. Documents you received?</p> <p>9 A. In some cases, yes.</p> <p>10 Q. Documents that you don't appear</p> <p>11 to have been copied on but were, nonetheless, in</p> <p>12 your area of responsibility?</p> <p>13 MS. VANNI: Objection.</p> <p>14 THE WITNESS: Yeah, yes.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Okay. Were you shown documents</p> <p>17 by counsel for any of the other defendants?</p> <p>18 A. Other than Endo?</p> <p>19 Q. Yes.</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Which defendant?</p> <p>22 A. H.D. Smith.</p> <p>23 Q. And did those refresh your</p> <p>24 recollection as well?</p>	<p style="text-align: right;">Page 108</p> <p>1 Endo, you went off to H.D. Smith?</p> <p>2 A. Yes.</p> <p>3 Q. Had a little consulting gig after</p> <p>4 that, right?</p> <p>5 MS. VANNI: Object to form.</p> <p>6 THE WITNESS: I was consulting.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. For nine months?</p> <p>9 A. Yes.</p> <p>10 Q. I didn't say that disparagingly.</p> <p>11 I'm just trying to fill out your full history so</p> <p>12 we can drill down a little bit.</p> <p>13 You were at H.D. Smith from 2014</p> <p>14 to 2016. From 2016 to 2017, you remained</p> <p>15 Pennsylvania based or came back here to</p> <p>16 Pennsylvania --</p> <p>17 A. Yes.</p> <p>18 Q. -- and were a regulatory</p> <p>19 consultant or compliance consultant from here,</p> <p>20 correct?</p> <p>21 A. Correct.</p> <p>22 Q. Did you consult for any of your</p> <p>23 former clients during that period of time? I</p> <p>24 shouldn't -- withdrawn.</p>
<p style="text-align: right;">Page 107</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And what subject areas</p> <p>3 were those?</p> <p>4 A. SOM. I think that's -- mostly</p> <p>5 SOM.</p> <p>6 Q. Okay. And what documents were</p> <p>7 you shown?</p> <p>8 MR. LEEDER: Objection?</p> <p>9 MR. BUCHANAN: We've already had</p> <p>10 the instruction on the record. You're</p> <p>11 going to have to instruct the witness</p> <p>12 not to answer.</p> <p>13 MR. LEEDER: I've already raised</p> <p>14 this objection with Mr. Young, and I</p> <p>15 will ask the witness not to answer the</p> <p>16 question.</p> <p>17 MR. BUCHANAN: Unless he</p> <p>18 instructs you not to answer the -- I</p> <p>19 just -- I need to be clear, are you</p> <p>20 instructing witness not to --</p> <p>21 MR. LEEDER: I'm instructing the</p> <p>22 witness not to answer the question.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. All right. So after you left</p>	<p style="text-align: right;">Page 109</p> <p>1 Did you consult for any of the</p> <p>2 former employers we've already talked about</p> <p>3 during that period of time?</p> <p>4 A. I did not.</p> <p>5 Q. Okay. Since leaving Endo, have</p> <p>6 you done consulting for Endo?</p> <p>7 MS. VANNI: Object to the form.</p> <p>8 THE WITNESS: No.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Since leaving H.D. Smith, have</p> <p>11 you done consulting for H.D. Smith?</p> <p>12 A. No.</p> <p>13 Q. Since leaving -- I said Endo. I</p> <p>14 should have said Qualitest.</p> <p>15 Since leaving Qualitest, have you</p> <p>16 done work for Qualitest?</p> <p>17 A. No.</p> <p>18 Q. Okay. So, too, for any of the</p> <p>19 other manufacturers, distributors you've worked</p> <p>20 for, correct?</p> <p>21 A. Correct.</p> <p>22 Q. Who did you work for, then, in</p> <p>23 that period of time -- withdrawn. Let me be</p> <p>24 more precise.</p>



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<p>1 Did you work for any</p> <p>2 manufacturers of controlled substances or</p> <p>3 distributors of controlled substances that you</p> <p>4 believe are defendants in this case?</p> <p>5 A. No.</p> <p>6 Q. Okay. Did you work for any</p> <p>7 manufacturers or distributors of controlled</p> <p>8 substances?</p> <p>9 A. Yes.</p> <p>10 Q. Who?</p> <p>11 A. For Neos Therapeutics.</p> <p>12 Q. Okay. And they brought you on</p> <p>13 board?</p> <p>14 A. Yes, they did.</p> <p>15 Q. Okay. Texas was too far, so you</p> <p>16 lasted for a year and then you came back here?</p> <p>17 A. No.</p> <p>18 Q. Okay.</p> <p>19 A. I did not relocate to Texas. I</p> <p>20 worked from -- from my home in Bethlehem and</p> <p>21 went to Texas one week a month.</p> <p>22 Q. Okay. All right. So I think we</p> <p>23 understand at this point, ma'am, to recap,</p> <p>24 you've got about 30 years' experience dealing</p>	<p>1 A. Closer to -- closer to my</p> <p>2 leaving, closer to the end of my work. Mostly I</p> <p>3 did not report to him for a long period of time.</p> <p>4 Q. Okay. So you had different</p> <p>5 people you reported to over time, but at the end</p> <p>6 of your tenure at Qualitest, the person you</p> <p>7 reported to is the chief operating officer,</p> <p>8 correct?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. That person was for the</p> <p>11 pharmaceutical division?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And who was that person?</p> <p>14 A. Don Degoyler.</p> <p>15 Q. Okay. And you had interactions</p> <p>16 with him from time to time?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 THE WITNESS: Occasionally.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. Let's talk about Qualitest.</p> <p>21 Qualitest is a manufacturer and</p> <p>22 distributor of controlled substances, true?</p> <p>23 A. They were.</p> <p>24 Q. Among other things?</p>
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<p>1 with controlled substances in some capacity or</p> <p>2 another, fair?</p> <p>3 A. Yes.</p> <p>4 Q. At various points at time and at</p> <p>5 times I'm going to drill down on in particular</p> <p>6 during your time at Qualitest, you were the DEA</p> <p>7 compliance manager, correct?</p> <p>8 A. The director of DEA compliance,</p> <p>9 yes.</p> <p>10 Q. Okay. You were the most senior</p> <p>11 person on DEA compliance?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. I mean, there are org</p> <p>14 charts, and we could look at them if we wanted</p> <p>15 to just make a big pile of exhibits over there,</p> <p>16 but there's org charts from your time at</p> <p>17 Qualitest that reflect you reported directly to</p> <p>18 the chief operating officer; is that correct?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: For a short period</p> <p>21 of time, yes.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. Okay. And what was that period</p> <p>24 of time?</p>	<p>1 A. They were, yes.</p> <p>2 Q. Okay. Roughly 70% of their</p> <p>3 business was controlled substances, do you</p> <p>4 remember that?</p> <p>5 MS. VANNI: Objection.</p> <p>6 THE WITNESS: If I had to guess,</p> <p>7 yes, about that.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. I mean, they made a lot of</p> <p>10 controlled substances, true?</p> <p>11 A. Yes, they did.</p> <p>12 Q. Okay. And they had these</p> <p>13 facilities, what is it, in Huntsville, Alabama</p> <p>14 and Charlottesville where they did all that</p> <p>15 manufacturing?</p> <p>16 A. Charlotte, North Carolina.</p> <p>17 Q. I think I said Charlottesville.</p> <p>18 That would be Virginia, right?</p> <p>19 A. Yes.</p> <p>20 Q. Charlotte, North Carolina.</p> <p>21 A. Correct.</p> <p>22 Q. Charlottesville, Virginia. And</p> <p>23 they don't have a place in Charlottesville,</p> <p>24 Virginia, right?</p>

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<p style="text-align: right;">Page 114</p> <p>1 A. They did not.</p> <p>2 Q. So Charlotte, North Carolina,</p> <p>3 Huntsville, Alabama is where they're making all</p> <p>4 these pills, correct?</p> <p>5 MS. VANNI: Object to form.</p> <p>6 THE WITNESS: That's where they</p> <p>7 had facilities, yes.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. Okay. And to be clear, I mean,</p> <p>10 billions and billions of pills, right?</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: I didn't keep track</p> <p>13 of total quantities.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Do you have -- do you have a</p> <p>16 sense that they were making a lot of them?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 THE WITNESS: There was a</p> <p>19 diverse -- diverse range of products.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Okay. I mean, you've been to the</p> <p>22 manufacturing facilities, right?</p> <p>23 A. Mm-hmm.</p> <p>24 Q. Yes?</p>	<p style="text-align: right;">Page 116</p> <p>1 drugs?</p> <p>2 MS. VANNI: Objection.</p> <p>3 THE WITNESS: I would not</p> <p>4 classify them as dangerous. When used</p> <p>5 appropriately, they're products that are</p> <p>6 approved by FDA for legitimate purposes.</p> <p>7 I wouldn't necessarily characterize them</p> <p>8 as dangerous.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Okay. Got to keep them in</p> <p>11 vaults, right?</p> <p>12 A. Yes.</p> <p>13 Q. Cages, right?</p> <p>14 A. Yes.</p> <p>15 Q. Two people watching everybody at</p> <p>16 all times, right?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Right?</p> <p>20 A. In some instances, two people.</p> <p>21 Q. Don't put on the outside of the</p> <p>22 box what's on the inside of the box because</p> <p>23 they're very prone to being stolen, diverted,</p> <p>24 abused, right?</p>
<p style="text-align: right;">Page 115</p> <p>1 A. Yes.</p> <p>2 Q. Sorry. We're kind of getting</p> <p>3 loose there.</p> <p>4 And I mean, these controlled</p> <p>5 substances -- and let's dial back for a second.</p> <p>6 The DEA framework makes it a</p> <p>7 closed system, right?</p> <p>8 A. Correct.</p> <p>9 Q. And you've got a -- I mean,</p> <p>10 there's so much concern about these drugs that</p> <p>11 you've got to store them in vaults and in cages</p> <p>12 and have special procedures around the incoming</p> <p>13 shipments and the outgoing shipments to make</p> <p>14 sure you're not losing pills anywhere in the</p> <p>15 process, right?</p> <p>16 MS. VANNI: Objection.</p> <p>17 THE WITNESS: There is an entire</p> <p>18 set of regulations governing the control</p> <p>19 of them, yes.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. But, I mean, you as somebody in</p> <p>22 DEA compliance for companies that, you know,</p> <p>23 deal in controlled substances over the years, I</p> <p>24 mean, you recognize that these are dangerous</p>	<p style="text-align: right;">Page 117</p> <p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: There is a</p> <p>3 diversion potential, abuse potential,</p> <p>4 yes.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. And that's not something you've</p> <p>7 come to learn about in 2019; that's something</p> <p>8 you've known about for 25 years, right?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: I've learned more</p> <p>11 over the years, yes.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. Right, but I mean, these -- these</p> <p>14 drugs, certainly if we're talking about</p> <p>15 Oxycontin, these are Morphine derivatives,</p> <p>16 right?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. Opiates have been around for a</p> <p>21 long time, right?</p> <p>22 A. Yes.</p> <p>23 Q. Since before the Controlled</p> <p>24 Substance Act, right?</p>

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<p style="text-align: right;">Page 118</p> <p>1 A. Yes.</p> <p>2 Q. And there's stories -- did you go</p> <p>3 and get a Master's in pharmacy?</p> <p>4 A. It's a Master's in pharmaceutical</p> <p>5 policy and regulation.</p> <p>6 Q. So you learned the regulations,</p> <p>7 you learned the case law I saw as well in your</p> <p>8 resume, right?</p> <p>9 A. Yes, some.</p> <p>10 Q. And so you saw how the Controlled</p> <p>11 Substances Act came about, correct?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. You are aware that these drugs</p> <p>16 have been drugs of abuse for a long time, right?</p> <p>17 MS. VANNI: Objection.</p> <p>18 THE WITNESS: The abuse of</p> <p>19 controlled substances has changed</p> <p>20 drastically over the years, different --</p> <p>21 different products, different entities</p> <p>22 at different times.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Right.</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. Who was the head of DEA</p> <p>2 compliance for Endo?</p> <p>3 A. There was -- there were several</p> <p>4 people that handled DEA compliance. They didn't</p> <p>5 necessarily have that title, from what I can</p> <p>6 recall.</p> <p>7 Q. Did -- Endo makes controlled</p> <p>8 substances, right?</p> <p>9 A. Endo outsourced controlled</p> <p>10 substances, so they didn't necessarily hold a</p> <p>11 license. They used contract manufacturers, so</p> <p>12 the DEA person would really be at that contract</p> <p>13 manufacturer for the most part.</p> <p>14 Q. Am I correct there is no head of</p> <p>15 DEA compliance for Endo?</p> <p>16 MS. VANNI: Objection.</p> <p>17 THE WITNESS: Not that I knew of.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Okay. If you were looking to</p> <p>20 have a conversation with a counterparty at Endo</p> <p>21 on DEA compliance issues, there was not a person</p> <p>22 like yourself on the other side of the building?</p> <p>23 MS. VANNI: Objection.</p> <p>24 THE WITNESS: Not with that</p>
<p style="text-align: right;">Page 119</p> <p>1 And, for example, back in the</p> <p>2 '70s, there was a drug known as oxymorphone.</p> <p>3 Have you heard of oxymorphone?</p> <p>4 A. Yes.</p> <p>5 Q. Controlled substances?</p> <p>6 A. Yes.</p> <p>7 Q. Withdrawn from the market?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: I'm not aware of</p> <p>10 that.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Due to abuse?</p> <p>13 Have you heard of numorphan?</p> <p>14 A. No.</p> <p>15 Q. You only -- when you were at</p> <p>16 Qualitest, you only had exposure to the generic</p> <p>17 products, not the branded products?</p> <p>18 A. Yes, for the most part.</p> <p>19 Q. Okay. If I understand, your silo</p> <p>20 of responsibilities with regard to DEA</p> <p>21 compliance was strictly on the Qualitest side?</p> <p>22 A. I would be consulted occasionally</p> <p>23 for the brand side, but my responsibilities were</p> <p>24 directed at the generic side.</p>	<p style="text-align: right;">Page 121</p> <p>1 title, but the knowledge was there.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. With who?</p> <p>4 A. Some with Jill Connell, who was</p> <p>5 my boss when I started. With Sanjay Patel, who</p> <p>6 later came in. With Lisa Walker. Doug Felton</p> <p>7 was another individual.</p> <p>8 There was -- there was just a</p> <p>9 good level of DEA knowledge, I think, at the</p> <p>10 Endo headquarters from what I experienced.</p> <p>11 Q. So there wasn't a DEA compliance</p> <p>12 person, per se, correct?</p> <p>13 MS. VANNI: Object to form.</p> <p>14 THE WITNESS: Correct.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. In your resume, you talk about</p> <p>17 having to comply with OIG orders and CIAs for</p> <p>18 other manufacturers.</p> <p>19 During your time at Qualitest,</p> <p>20 were there any CIAs or other orders, regulatory</p> <p>21 orders that you were charged with enforcing?</p> <p>22 A. I'm sorry, CIAs?</p> <p>23 Q. Agreements with the Department of</p> <p>24 Justice resolving allegations, claims where the</p>

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<p style="text-align: right;">Page 122</p> <p>1 company committed to do things in a certain way.</p> <p>2 A. No.</p> <p>3 Q. Okay. From a compliance</p> <p>4 perspective at Qualitest, your compliance was</p> <p>5 focused on the regulatory framework, the</p> <p>6 statutory framework and, if you will, the</p> <p>7 industry framework, correct?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Okay. All right. So let's just</p> <p>12 kind of put a fine point on Qualitest's</p> <p>13 business.</p> <p>14 (Document marked for</p> <p>15 identification as Par-Norton Deposition</p> <p>16 Exhibit No. 4.)</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Passing you what's been marked as</p> <p>19 Exhibit 4. It's 1157.</p> <p>20 MR. BUCHANAN: Bradley, if you</p> <p>21 could pull it up.</p> <p>22 MS. VANNI: Do you have a copy</p> <p>23 for me?</p> <p>24 MR. BUCHANAN: Oh, I'm sorry.</p>	<p style="text-align: right;">Page 124</p> <p>1 Yours should be as well.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Do you have two pages, ma'am?</p> <p>4 A. Yes.</p> <p>5 Q. So on the screen, we see a chart,</p> <p>6 and this chart was prepared by our office from</p> <p>7 the spreadsheets that are referenced here and</p> <p>8 using the data that your counsel has pointed us</p> <p>9 to, to reflect the shipping data for Par</p> <p>10 products.</p> <p>11 Qualitest was ultimately -- I'm</p> <p>12 sorry, Par was ultimately acquired by Endo, and</p> <p>13 the Qualitest business went into Par.</p> <p>14 Do you have that understanding?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. All right. So this is</p> <p>17 looking back in time, and there's a list of</p> <p>18 products on the left.</p> <p>19 Do you see those?</p> <p>20 A. Yes, I do.</p> <p>21 Q. Okay. Some of these are</p> <p>22 controlled substances and CS2, some are CS3,</p> <p>23 some are Schedule I, right?</p> <p>24 A. There are no Schedule I.</p>
<p style="text-align: right;">Page 123</p> <p>1 MS. VANNI: Thank you.</p> <p>2 MR. BUCHANAN: I need one back,</p> <p>3 actually. Keep that in the folder.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. We're marking as Exhibit 4 a</p> <p>6 summary of Qualitest shipments.</p> <p>7 MS. VANNI: Counsel, I'm assuming</p> <p>8 this is produced in native, but could</p> <p>9 you read the Bates number into this.</p> <p>10 MR. BUCHANAN: Yeah, the Bates</p> <p>11 number is -- so this -- we've asked you</p> <p>12 for your shipping information, and</p> <p>13 you've pointed us to this particular</p> <p>14 document. I guess I could ask the</p> <p>15 witness to sum it, but that would be a</p> <p>16 poor use of our day together, but the</p> <p>17 Bates numbers at the top Par Opioid</p> <p>18 MDL0001596805, Par Opioid</p> <p>19 MDL00015968013-68019. I believe these</p> <p>20 are spreadsheets that you have produced</p> <p>21 to us.</p> <p>22 MS. VANNI: And it's one page or</p> <p>23 two?</p> <p>24 MR. BUCHANAN: Mine is two pages.</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. Oh, I don't see -- that would be</p> <p>2 what, pseudoephedrine-type products?</p> <p>3 A. No, a Schedule I drug has no</p> <p>4 medical use in the United States. If you are</p> <p>5 referring to pseudoephedrine, that's a List I</p> <p>6 chemical.</p> <p>7 Q. Thank you. That's what I was</p> <p>8 trying to convey.</p> <p>9 And we don't have List I</p> <p>10 chemicals on here, correct?</p> <p>11 A. Correct.</p> <p>12 Q. So these are products. Which of</p> <p>13 these of Schedule II, ma'am?</p> <p>14 A. The Endocet, the Endodan,</p> <p>15 hydrocodone products, ibudone I believe is</p> <p>16 Schedule II. Some of the ones in the middle,</p> <p>17 Peritab I'm not sure of. Morphine is Schedule</p> <p>18 II. Opana is Schedule II. Oxycodone,</p> <p>19 oxymorphone, Percocet -- most of them are</p> <p>20 Schedule II.</p> <p>21 Meperidine, I believe, is</p> <p>22 Schedule IV.</p> <p>23 Q. And then we can see at the bottom</p> <p>24 of each of these the products of these various</p>

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<p>1 products by year. I guess if we looked over</p> <p>2 time -- and we only have data going back to</p> <p>3 2008, we don't have it past 2015.</p> <p>4 So if we looked at oxycodone, for</p> <p>5 example, and you told us before that was</p> <p>6 Oxycontin, right? That's the active</p> <p>7 pharmaceutical ingredient?</p> <p>8 A. In the brand, in the brand.</p> <p>9 Q. In branded form, it's Oxycontin,</p> <p>10 correct?</p> <p>11 A. Mm-hmm.</p> <p>12 Q. So, you know, roughly 2.8, 2.9,</p> <p>13 is that million pills or billion pills, ma'am?</p> <p>14 2.8 million?</p> <p>15 A. Yes.</p> <p>16 Q. It's billion, right?</p> <p>17 MS. VANNI: Where are you</p> <p>18 looking?</p> <p>19 THE WITNESS: The total.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. 2.8 billion pills?</p> <p>22 A. Mm-hmm.</p> <p>23 Q. Wow. That's a lot.</p> <p>24 MS. VANNI: Object to form.</p>	<p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: It appears that</p> <p>3 way.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. Can we agree that's a lot?</p> <p>6 MS. VANNI: Objection.</p> <p>7 THE WITNESS: It depends on the</p> <p>8 scenario. I don't know what's a lot</p> <p>9 versus a little. It's not something</p> <p>10 that I was involved in or --</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. I mean, close to ten pills for</p> <p>13 every human being in the United States --</p> <p>14 MS. VANNI: Objection.</p> <p>15 BY MR. BUCHANAN</p> <p>16 Q. -- over a seven-year period of</p> <p>17 time --</p> <p>18 MS. VANNI: Objection.</p> <p>19 THE WITNESS: Mm-hmm.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. -- does that qualify as a lot to</p> <p>22 you --</p> <p>23 MS. VANNI: Objection.</p> <p>24 BY MR. BUCHANAN:</p>
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<p>1 BY MR. BUCHANAN:</p> <p>2 Q. Could we agree?</p> <p>3 MS. VANNI: Objection.</p> <p>4 THE WITNESS: I don't know -- the</p> <p>5 data that I'm looking at, I'm not sure</p> <p>6 where it's coming from. And when you're</p> <p>7 talking shipments -- so a shipment in</p> <p>8 DEA's mind could be a transfer from one</p> <p>9 location to another. It's not</p> <p>10 necessarily a sale to a customer. I</p> <p>11 don't know which facility this is</p> <p>12 referring to, which -- and, you know,</p> <p>13 whether it's big or small is opinion.</p> <p>14 So...</p> <p>15 BY MR. BUCHANAN</p> <p>16 Q. Okay. And we could fuss with the</p> <p>17 data. That would probably require me to fuss</p> <p>18 with your counsel because this is what they've</p> <p>19 pointed us to for the sales of the product.</p> <p>20 A. Mm-hmm.</p> <p>21 Q. Let's just talk about a number, I</p> <p>22 guess. If we're counting the zeros here right,</p> <p>23 2.88 billion pills of oxycodone, one formulation</p> <p>24 of the oxycodone, correct?</p>	<p>1 Q. -- from one manufacturer?</p> <p>2 MS. VANNI: Objection.</p> <p>3 THE WITNESS: I can't make that</p> <p>4 determination.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Okay. And that's just one, one</p> <p>7 item on this sheet.</p> <p>8 We've got oxycodone APAP</p> <p>9 combinations. That's 533 million, right?</p> <p>10 A. Yes.</p> <p>11 Q. They're up to 3.3, 3.4 billion</p> <p>12 pills of Oxycontin or Oxycontin combinations.</p> <p>13 How about -- you talked about</p> <p>14 Vicodin before, you said that's a schedule drug,</p> <p>15 right?</p> <p>16 A. Yes.</p> <p>17 Q. Do you see the generic equivalent</p> <p>18 of Vicodin on this sheet, ma'am?</p> <p>19 A. The Hydrocodone product?</p> <p>20 Q. Okay. Let's look up there.</p> <p>21 MR. BUCHANAN: Can you highlight</p> <p>22 the two hydrocodones. There you go.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. All right. Is that 3 billion?</p>



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<p style="text-align: right;">Page 130</p> <p>1 That's 33 billion. 33 billion pills, right?</p> <p>2 33 billion Vicodins Qualitest made and shipped</p> <p>3 between 2008 and 2015?</p> <p>4 MS. VANNI: Objection.</p> <p>5 THE WITNESS: Again, I don't -- I</p> <p>6 can't comment on this data. There's not</p> <p>7 enough information here. I don't know</p> <p>8 what the background is. I don't know</p> <p>9 what's a lot and what's a small amount.</p> <p>10 I mean, I'm not a physician, I'm not one</p> <p>11 to make a determination of small versus</p> <p>12 large.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. A hundred Vicodin for every human</p> <p>15 being of every age in the United States?</p> <p>16 MS. VANNI: Objection.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Is that a lot to you?</p> <p>19 A. I don't know.</p> <p>20 MS. VANNI: Objection.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Well, when you were the head of</p> <p>23 DEA compliance for Qualitest, did you have the</p> <p>24 sense, ma'am, that -- this company was pumping</p>	<p style="text-align: right;">Page 132</p> <p>1 Am I doing my math right, ma'am?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. Does that look right to you, 25,</p> <p>5 \$26 billion in just Vicodin?</p> <p>6 MS. VANNI: Object to the form.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. Right?</p> <p>9 A. Again, can't comment on the</p> <p>10 financials. I didn't get involved with the</p> <p>11 financials.</p> <p>12 Q. I mean, does this help clarify</p> <p>13 for you, ma'am, this is actually sale and</p> <p>14 shipping data?</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: No, because a sale</p> <p>17 is also a transfer. When you're -- when</p> <p>18 you're talking about a movement from a</p> <p>19 distributor, you know, I don't know</p> <p>20 whether this is a movement from</p> <p>21 Qualitest distribution to a storage</p> <p>22 location, if it's a movement from a</p> <p>23 manufacturer to a distributor. I don't</p> <p>24 have any -- and even if I did, I can't</p>
<p style="text-align: right;">Page 131</p> <p>1 out controlled substances at this rate?</p> <p>2 MS. VANNI: Objection.</p> <p>3 THE WITNESS: We were a large</p> <p>4 manufacturer and distributor of</p> <p>5 controlled products. I'm sure there</p> <p>6 were larger.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. There's other people -- somebody</p> <p>9 made -- this is just you, right? This is just</p> <p>10 one manufacturer, Qualitest, right?</p> <p>11 A. And again --</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: -- you don't know</p> <p>14 whether these are sales, whether these</p> <p>15 are shipments for transfer. This is not</p> <p>16 conclusive.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Well, so if we go to the next</p> <p>19 sheet, the company gave us the dollars and the</p> <p>20 sales for these; do you see that?</p> <p>21 A. Mm-hmm.</p> <p>22 Q. And they're telling us, if you</p> <p>23 highlight those two hydrocodone lines, what is</p> <p>24 that, looks like about \$25 billion in sales.</p>	<p style="text-align: right;">Page 133</p> <p>1 comment on whether that amount is large,</p> <p>2 small. Not something that I dealt with.</p> <p>3 I don't have anything to compare it to,</p> <p>4 in other words.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Okay. I mean, did you have the</p> <p>7 sense, though, ma'am, that the company during</p> <p>8 your tenure was pumping out billions and</p> <p>9 billions and billions of Vicodin every year?</p> <p>10 MS. VANNI: Objection.</p> <p>11 THE WITNESS: The company was an</p> <p>12 ongoing manufacturer of controlled</p> <p>13 substances.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Okay. And so very important, if</p> <p>16 you're manufacturing enough Vicodin to give</p> <p>17 every human being, living person in the United</p> <p>18 States 100 pills from just your manufacturing</p> <p>19 facility, very important if you're that type of</p> <p>20 manufacturer to make sure you are maintaining a</p> <p>21 closed system with effective controls against</p> <p>22 diversion, true?</p> <p>23 MS. VANNI: Objection.</p> <p>24 THE WITNESS: Any -- any</p>

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<p style="text-align: right;">Page 134</p> <p>1 controlled substance manufacturer, it's</p> <p>2 important.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. That's right. Top to bottom, if</p> <p>5 you're making a million, a million pills can</p> <p>6 cause a lot of problems, right?</p> <p>7 MS. VANNI: Objection.</p> <p>8 THE WITNESS: If they make it out</p> <p>9 of the legitimate channel.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Right.</p> <p>12 I mean, if you're just a small</p> <p>13 manufacturer, you still have to keep this stuff</p> <p>14 in a vault, right?</p> <p>15 A. Schedule I and II, yes.</p> <p>16 MS. VANNI: Objection.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Schedule II, we're talking about</p> <p>19 hydrocodone, right?</p> <p>20 A. Yes.</p> <p>21 Q. Hydrocodone is Schedule II?</p> <p>22 A. For part of the -- part of my</p> <p>23 time at Qualitest, hydrocodone was Schedule III,</p> <p>24 which would require it to be in a cage, not a</p>	<p style="text-align: right;">Page 136</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Make sure it's only getting to</p> <p>3 customers who are getting it for legitimate</p> <p>4 purposes, right?</p> <p>5 A. Yes.</p> <p>6 Q. Make sure that your customers</p> <p>7 have processes in place so that they're using it</p> <p>8 only for legitimate purposes, right?</p> <p>9 A. To the best of your ability, yes.</p> <p>10 Q. So that you maintain this closed</p> <p>11 system of distribution because we know at some</p> <p>12 point in time, it's not going to be in a safe,</p> <p>13 right?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: At the pharmacy</p> <p>16 level, at the physician -- yes.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. And, ultimately, these are drugs</p> <p>19 that cause lots of problems, right?</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: These are drugs</p> <p>22 that have a legitimate medical purpose</p> <p>23 and serve a legitimate need when used</p> <p>24 properly.</p>
<p style="text-align: right;">Page 135</p> <p>1 vault, but that changed.</p> <p>2 Q. Right.</p> <p>3 So that's what, 2013 or so, it</p> <p>4 changed schedule from --</p> <p>5 A. 2013, 2014. I'm not exactly</p> <p>6 sure.</p> <p>7 Q. Okay. You still had to keep it</p> <p>8 in the cage?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Schedule II has to be in a vault,</p> <p>13 a safe?</p> <p>14 A. Safe for small quantities, yes.</p> <p>15 Q. Right. Right.</p> <p>16 So even if you are a manufacturer</p> <p>17 that's not putting out 35 billion pills of</p> <p>18 Vicodin or selling \$25 billion worth of it,</p> <p>19 you've got to watch this stuff like a hawk,</p> <p>20 right?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: You have to follow</p> <p>23 the regulations regardless of the</p> <p>24 quantities.</p>	<p style="text-align: right;">Page 137</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. These are drugs that wreak havoc</p> <p>3 in our communities, would you agree?</p> <p>4 MS. VANNI: Objection.</p> <p>5 THE WITNESS: No, I would not</p> <p>6 agree.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. These are drugs that wreak havoc</p> <p>9 and devastating consequences in our community,</p> <p>10 do you agree, ma'am?</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: The drugs that were</p> <p>13 manufactured at companies that I worked</p> <p>14 for went to legitimate entities.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Pardon me for a moment.</p> <p>17 Is there some debate in your</p> <p>18 mind, ma'am, as to whether or not these drugs,</p> <p>19 Oxycontin, oxycodone, oxymorphone, hydrocodone</p> <p>20 wreak havoc in our communities?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: The drugs do have</p> <p>23 abuse potential. What I'm saying is</p> <p>24 that the products that were made at the</p>

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<p style="text-align: right;">Page 138</p> <p>1 companies that I worked for were kept 2 under control and are not the 3 products -- well, not the tablets that 4 are wreaking havoc in the community, as 5 you put it. 6 (Document marked for 7 identification as Par-Norton Deposition 8 Exhibit No. 5.) 9 MR. BUCHANAN: Passing what we're 10 marking as Exhibit 5 to your deposition. 11 Copy for you, Counsel. Actually, 12 keep one, please. Make sure you keep 13 one. 14 MS. VANNI: Thank you. 15 BY MR. BUCHANAN: 16 Q. We're calling this Exhibit 5. 17 Ma'am, this is a letter that you 18 put together in 2013; is that right? 19 A. It is a letter I put together, 20 yes, 2013. 21 Q. And this is after you had the 22 meeting with the DEA and -- 23 MS. VANNI: Counsel, did this 24 come from Qualitest's file or ABC or --</p>	<p style="text-align: right;">Page 140</p> <p>1 meeting wasn't a required meeting. It 2 was something that we requested. 3 BY MR. BUCHANAN: 4 Q. And this was one of the things 5 you were doing in advance of that meeting, fair? 6 A. This is something we were working 7 on making improvements to the SOM program before 8 we met with DEA. 9 Q. All right. So what you wrote 10 here in October 18, 2013 -- go back to the first 11 page, please, Bradley. 12 "Dear valued customers, as you 13 may be aware, a large percentage of Qualitest 14 products are categorized as controlled 15 substances or listed chemicals." 16 True statement, right? 17 A. Yes. 18 Q. In fact, 70% were controlled 19 substances, right? 20 A. Approximately, yes. 21 Q. I mean, that was very much what 22 Qualitest's business was, was the manufacture 23 and sale of controlled substances, correct? 24 MS. VANNI: Object to form.</p>
<p style="text-align: right;">Page 139</p> <p>1 I'm just not understanding the 2 designation at the bottom. 3 MR. BUCHANAN: You know, that's a 4 good question. I believe if it says 5 ABDCMDL, I assume it's 6 AmerisourceBergen. For the record, 7 Exhibit 5 is Bates-stamped 8 ABDCMDL00337067. 9 BY MR. BUCHANAN: 10 Q. Let's go to point 3. You see the 11 Qualitest letterhead? 12 A. Yes. 13 Q. This is, in fact, a letter from 14 you if you turn to the next page, right? 15 A. Yes, it is. 16 Q. You sent a letter out to your 17 customers, right? 18 A. Yes, we did. 19 Q. And this was before you were 20 going to have that follow-up meeting with the 21 DEA after your first meeting with the DEA on the 22 SOMs issues, correct? 23 MS. VANNI: Object to form. 24 THE WITNESS: The follow-up</p>	<p style="text-align: right;">Page 141</p> <p>1 THE WITNESS: Yes. 2 BY MR. BUCHANAN: 3 Q. And these products, while 4 necessary for patients, can be targets for abuse 5 and diversion, right? 6 A. Yes. 7 Q. You had that knowledge certainly 8 in 2013, right? 9 A. Yes. 10 Q. And you knew that because you had 11 been working on it all the way back in your 12 Ciba-Geigy days, right? 13 MS. VANNI: Object to form. 14 BY MR. BUCHANAN: 15 Q. True? 16 A. Yes. 17 Q. Right. 18 "As a result, certain Qualitest 19 products have become highly desirable to those 20 seeking to abuse or divert for profit." 21 Do you see that? 22 A. Yes. 23 Q. And so you certainly had that 24 knowledge as of 2013 that Qualitest's products,</p>

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<p style="text-align: right;">Page 142</p> <p>1 your products, were highly desirable to those</p> <p>2 who were abusing or seeking to, you know, get</p> <p>3 them out of the normal channels, right?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Yes, ma'am?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And you stated when your</p> <p>9 products leave legitimate channels, they've been</p> <p>10 manufactured to support, what did you say?</p> <p>11 A. "Heart-wrenching consequences</p> <p>12 often occur."</p> <p>13 Q. Often occur, right?</p> <p>14 A. That's what we were being told by</p> <p>15 DEA, yes.</p> <p>16 Q. You had that knowledge, right?</p> <p>17 A. From attending DEA conferences,</p> <p>18 yes.</p> <p>19 Q. You didn't have to go to DEA</p> <p>20 conferences. You could read the New York Times,</p> <p>21 you could read your local paper here in</p> <p>22 Bethlehem, Pennsylvania and see that Congress is</p> <p>23 holding hearings, that Purdue is getting</p> <p>24 sanctioned to the tune of \$650 million for its</p>	<p style="text-align: right;">Page 144</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Is that a true statement?</p> <p>4 A. Yes. Yes, it is. And you know</p> <p>5 what --</p> <p>6 Q. We know in the early 2000s --</p> <p>7 sorry. If you were going to add something --</p> <p>8 A. Okay.</p> <p>9 Q. Okay. In the early 2000s, there</p> <p>10 were congressional hearings about Oxycontin</p> <p>11 abuse, do you remember that?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: Vaguely, yes.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Oxycontin is oxycodone, correct?</p> <p>16 A. Yes.</p> <p>17 Q. If we went back to that slide --</p> <p>18 jeez, or that exhibit, we don't have to, it's</p> <p>19 Exhibit 4, you have it before you, ma'am, and</p> <p>20 you can see it, I was asking the trial tech not</p> <p>21 to go back to it, but we can see, you know, some</p> <p>22 three-plus billion pills of oxycodone over a</p> <p>23 seven-year period of time, and you knew</p> <p>24 OxyContin was a drug of abuse, highly desirable</p>
<p style="text-align: right;">Page 143</p> <p>1 roles. You had that knowledge, ma'am, as</p> <p>2 somebody in the industry that these products are</p> <p>3 dangerous, right?</p> <p>4 MS. VANNI: Objection.</p> <p>5 THE WITNESS: Again, products</p> <p>6 that -- the products that we made at our</p> <p>7 facilities were under our control.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. Did you know there were</p> <p>10 congressional hearings --</p> <p>11 A. I'm not saying -- I'm not saying</p> <p>12 that hydrocodone is not a dangerous substance</p> <p>13 when used improperly.</p> <p>14 What I'm saying is that</p> <p>15 hydrocodone did not come from Qualitest.</p> <p>16 Q. What do you mean? We looked at</p> <p>17 it, you sold 33 billion pills of hydrocodone</p> <p>18 over seven years.</p> <p>19 A. Yes.</p> <p>20 Q. I mean, you were putting 100</p> <p>21 pills per person in this country out into the</p> <p>22 market. I mean, Qualitest drugs, Qualitest</p> <p>23 hydrocodone were in the market, true?</p> <p>24 MS. VANNI: Object to form.</p>	<p style="text-align: right;">Page 145</p> <p>1 to those in the community, right?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: Yes.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. And that's what you were telling</p> <p>6 the customers?</p> <p>7 A. Again, the sales do not -- the</p> <p>8 sales do not mean prescriptions.</p> <p>9 Q. Okay. Well, what you wrote here</p> <p>10 is "certain Qualitest products have become</p> <p>11 highly desirable to those seeking to abuse or</p> <p>12 divert for profit," right?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Certain Qualitest products</p> <p>15 that have become highly desirable, we can agree</p> <p>16 your hydrocodone preparations were highly</p> <p>17 desirable and attractive to those seeking to</p> <p>18 abuse or divert for profit, correct?</p> <p>19 A. Yes.</p> <p>20 Q. We can agree that your oxycodone</p> <p>21 products were highly desirable to those seeking</p> <p>22 to abuse or divert for profit, correct?</p> <p>23 A. Yes, and that's why we had</p> <p>24 appropriate controls in place.</p>

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<p style="text-align: right;">Page 146</p> <p>1 Q. Right.</p> <p>2 And that's why you're sending the</p> <p>3 letter out to your customers here, right?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And you thought this was a</p> <p>6 responsible thing to do, I take it?</p> <p>7 MS. VANNI: Object to form.</p> <p>8 THE WITNESS: We did.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Okay. And you noted that when</p> <p>11 the drugs leave legitimate channels, back to the</p> <p>12 second paragraph, they've been manufactured to</p> <p>13 support, heart-wrenching consequences often</p> <p>14 occur.</p> <p>15 I mean, you know what those</p> <p>16 heart-wrenching consequences are, right?</p> <p>17 A. Yes.</p> <p>18 Q. Death, right?</p> <p>19 A. Yes.</p> <p>20 Q. These are drugs that if somebody</p> <p>21 consumes too much, respiratory distress and</p> <p>22 death can ensue, correct?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 THE WITNESS: Yes.</p>	<p style="text-align: right;">Page 148</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Okay. "As a responsible</p> <p>3 corporate citizen," you said, "individuals,</p> <p>4 parents, friends, caregivers, relatives and</p> <p>5 acquaintances, we need to do as much as we can</p> <p>6 to prevent drug abuse and diversion in our</p> <p>7 communities."</p> <p>8 Did I read that correctly?</p> <p>9 A. Yes, you did.</p> <p>10 Q. And do you agree with that?</p> <p>11 A. Yes.</p> <p>12 Q. As a company who is selling</p> <p>13 33 billion pills or making 33 billion</p> <p>14 hydrocodone tablets or Vicodin equivalents, you</p> <p>15 need to do as much as you can to prevent</p> <p>16 diversion in your communities, fair?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 THE WITNESS: That's how I feel,</p> <p>19 yeah.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. As a manufacturer making</p> <p>22 3 billion oxycodone pills, you need to do as</p> <p>23 much as you can to prevent diversion in your</p> <p>24 community, right?</p>
<p style="text-align: right;">Page 147</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. I mean, there's a whole host of</p> <p>3 other dangerous things that can happen because</p> <p>4 of too much of these drugs other than death,</p> <p>5 right?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. Whether it's work relationships,</p> <p>10 family relationships, unproductivity, the full</p> <p>11 panoply of side effects that are described with</p> <p>12 these drugs when they're abused are</p> <p>13 heart-wrenching, correct?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: Yes, and it's</p> <p>16 documented on the label as such.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. And as responsible corporate</p> <p>19 citizens, this is what you wrote, right, and</p> <p>20 this is what you were trying to do for Qualitest</p> <p>21 at this point in time in 2013 was be a</p> <p>22 responsible corporate citizen, correct?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 THE WITNESS: Yes.</p>	<p style="text-align: right;">Page 149</p> <p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: And following the</p> <p>3 regulations does that, yes.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. And you said "we need to do as</p> <p>6 much as we can."</p> <p>7 Isn't that what you wrote?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And you believed it then,</p> <p>10 right?</p> <p>11 A. Yes.</p> <p>12 Q. And you believe it today, right?</p> <p>13 A. If we follow the regulations,</p> <p>14 then we are doing what we can, yes.</p> <p>15 Q. Oh, no, ma'am, you can do a lot</p> <p>16 more than the regulations. Those are minimum</p> <p>17 standards?</p> <p>18 A. And we have.</p> <p>19 Q. Right?</p> <p>20 A. Mm-hmm.</p> <p>21 MS. VANNI: Object to form.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. And so when you say "we can do as</p> <p>24 much as we can as responsible corporate</p>

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<p style="text-align: right;">Page 150</p> <p>1 citizens," you are saying we need to do what we</p> <p>2 can do, as much as we can to prevent diversion.</p> <p>3 That's what you wrote, correct?</p> <p>4 A. Yes, that's what I wrote.</p> <p>5 Q. Okay. "Each company and</p> <p>6 individual in the supply chain has that</p> <p>7 responsibility," right? Is that what you wrote?</p> <p>8 A. That's what I wrote.</p> <p>9 Q. Each company, each person has</p> <p>10 that responsibility to do as much as they can to</p> <p>11 prevent diversion, right?</p> <p>12 A. Yes.</p> <p>13 Q. Not just DEA regulations, as much</p> <p>14 as they can to prevent diversion, right?</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: That's what I</p> <p>17 wrote, yes.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Because heart-wrenching</p> <p>20 consequences can occur, correct?</p> <p>21 MS. VANNI: Form.</p> <p>22 THE WITNESS: That's what I</p> <p>23 wrote, yes.</p> <p>24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 152</p> <p>1 THE WITNESS: I don't recall who</p> <p>2 reviewed it, to be honest, but these</p> <p>3 were my personal words to begin with,</p> <p>4 and the intent of this letter was to</p> <p>5 educate and to tease that we might be</p> <p>6 asking to fill out a SOM questionnaire,</p> <p>7 who maybe weren't as familiar with the</p> <p>8 requirements.</p> <p>9 And, also, since we were doing</p> <p>10 this, I wanted them to have some</p> <p>11 background as to why we were asking for</p> <p>12 a questionnaire since we hadn't asked</p> <p>13 for a questionnaire previously to this</p> <p>14 extent.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. You had it reviewed by legal</p> <p>17 before it went out, right?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: Probably, yes.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. I mean, you wouldn't send a</p> <p>22 letter out to all the company's customers</p> <p>23 without having legal and sales and senior to you</p> <p>24 review it, right?</p>
<p style="text-align: right;">Page 151</p> <p>1 Q. "Everyone has that responsibility</p> <p>2 to put adequate controls in place to discourage</p> <p>3 and prevent the diversion of prescription</p> <p>4 products for uses other than those for which</p> <p>5 they were originally intended."</p> <p>6 Your words, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And not just your words, these</p> <p>9 were the head of DEA compliance for Qualitest's</p> <p>10 words, going out to all of its customers at this</p> <p>11 point in time, correct?</p> <p>12 A. Yes.</p> <p>13 MS. VANNI: Object to form.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. You had that responsibility,</p> <p>16 everyone had that responsibility, right?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 THE WITNESS: I like to think</p> <p>19 that, yes.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. And these were not just your</p> <p>22 personal words, right? This got reviewed at the</p> <p>23 highest levels in the company, didn't it?</p> <p>24 MS. VANNI: Object to form.</p>	<p style="text-align: right;">Page 153</p> <p>1 MS. VANNI: Objection.</p> <p>2 THE WITNESS: I don't know who</p> <p>3 reviewed it.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. Okay. I do have that for you.</p> <p>6 A. Okay.</p> <p>7 Q. See if I can find it.</p> <p>8 Let's continue with the letter</p> <p>9 while we're looking with the one to just firm up</p> <p>10 that fact, okay?</p> <p>11 A. Okay.</p> <p>12 Q. Moving into the second paragraph,</p> <p>13 you said you were going to be making some</p> <p>14 changes that might impact your customers, right?</p> <p>15 MS. VANNI: Third paragraph.</p> <p>16 MR. BUCHANAN: I'm sorry, yeah, I</p> <p>17 misspoke. Thank you.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. BUCHANAN</p> <p>20 Q. Making some changes that could</p> <p>21 impact your customers. One, you were enhancing</p> <p>22 your due diligence efforts when fulfilling</p> <p>23 orders, right?</p> <p>24 A. Yes.</p>

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<p style="text-align: right;">Page 154</p> <p>1 Q. You were looking to provide 2 greater assurance that your products are being 3 purchased by appropriate patients for prescribed 4 uses, right? 5 A. To gather data for that, yes. 6 Q. And as part of the enhanced 7 process, you were telling your customers you are 8 going to get some more frequent inquiries from 9 Qualitest regarding your own suspicious order 10 monitoring efforts, right? 11 A. Yes. 12 Q. You said if you are not able to 13 verify through inquiries and research that your 14 products are being used for legitimate purposes, 15 we may request an additional step of an on-site 16 visit of either your company or your customers, 17 right? 18 A. Yes, there were a number of 19 improvements we were trying to make. 20 Q. So, one, you wanted to ensure 21 that your customer was a legitimate customer, 22 that they were, in fact, a registrant, right? 23 A. Well, we knew that already, but 24 yes.</p>	<p style="text-align: right;">Page 156</p> <p>1 you really can't make a decision based 2 on one thing. It's the overall -- it's 3 the overall assessment that you have to 4 consider. 5 BY MR. BUCHANAN: 6 Q. Absolutely. Got to be a 7 comprehensive look, right? 8 A. Yes. 9 Q. A thorough knowledge of your 10 customers, right? 11 MS. VANNI: Object to form. 12 THE WITNESS: Yes. 13 BY MR. BUCHANAN: 14 Q. That's what's expected; know your 15 customer, correct? 16 MS. VANNI: Object to form. 17 THE WITNESS: Yes. 18 BY MR. BUCHANAN: 19 Q. Not only your customer, know your 20 customers' customer, right? 21 MS. VANNI: Object to form. 22 THE WITNESS: To the extent you 23 can. 24 BY MR. BUCHANAN:</p>
<p style="text-align: right;">Page 155</p> <p>1 Q. Two, you wanted to make sure that 2 they had protocols in place to monitor for 3 suspicious orders, right? 4 A. Yes. 5 Q. And you are going to start doing 6 due diligence visits, right? 7 A. Yes. 8 Q. Because, you know, if you go to a 9 pharmacy and there's no front-end merchandise 10 and there's a cage between the pharmacist and 11 the customers and there's a long line out the 12 front door, that starts to look a little 13 different than walking into your local -- your 14 local pharmacy that's got front-end merchandise, 15 a good balance of business and no lines out the 16 door, right? 17 A. Yes. 18 MS. VANNI: Object to form. 19 BY MR. BUCHANAN: 20 Q. Okay. And those are things you 21 can figure out just by walking in the door, 22 right? 23 MS. VANNI: Object to form. 24 THE WITNESS: I think for some,</p>	<p style="text-align: right;">Page 157</p> <p>1 Q. Right. 2 And so, you know, understand are 3 these distributors who you are selling -- you 4 can't just turn a blind eye because you're 5 selling just to a distributor, right? 6 MS. VANNI: Object to form. 7 THE WITNESS: Absolutely not. 8 BY MR. BUCHANAN: 9 Q. Right. 10 I mean, you have to understand 11 whether that distributor is acquiring drug to go 12 to for a legitimate medical purpose at the end 13 of that process, correct? 14 A. Yes. 15 Q. They have to have a customer base 16 of sound customers, correct? 17 A. Yes. 18 Q. And they have to have suspicious 19 order monitoring practices to determine that, 20 right? 21 MS. VANNI: Object to form. 22 THE WITNESS: Yes. 23 BY MR. BUCHANAN: 24 Q. We can't just let somebody in the</p>

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<p style="text-align: right;">Page 158</p> <p>1 supply chain put their head in the sand, right?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: Correct.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. That's very, very dangerous,</p> <p>6 right?</p> <p>7 MS. VANNI: Objection.</p> <p>8 THE WITNESS: Potentially, yes.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. We can't have a closed system of</p> <p>11 controlled substances if participants in that</p> <p>12 closed system are going to put their head in the</p> <p>13 sand, correct?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. And so one of your jobs and what</p> <p>18 you're saying in this letter is we're no longer</p> <p>19 going to put our head in the sand, right?</p> <p>20 MS. VANNI: Objection.</p> <p>21 THE WITNESS: No, that's not what</p> <p>22 we're saying at all.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. You are saying we're going to</p>	<p style="text-align: right;">Page 160</p> <p>1 of the original regulation or the original SOM</p> <p>2 requirements, and they're still not requirements</p> <p>3 today.</p> <p>4 Q. As a manufacturer of 35 billion</p> <p>5 pills who has got a responsibility to do</p> <p>6 everything they can to ensure that their product</p> <p>7 stays in the appropriate channels, you would</p> <p>8 agree with me, ma'am, that it is reasonable to</p> <p>9 do inspections of your customers, due diligence</p> <p>10 visits, correct?</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: In some -- of your</p> <p>13 direct customers, yes.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. It is further reasonable to</p> <p>16 ensure that your customers are doing the same</p> <p>17 thing with their customers, right?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: Not necessarily.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Okay. When your customers are</p> <p>22 wholesalers or distributors, you certainly want</p> <p>23 to make sure that they've got suspicious order</p> <p>24 monitoring protocols in place because they've</p>
<p style="text-align: right;">Page 159</p> <p>1 start doing some due diligence on you, right?</p> <p>2 MS. VANNI: Objection.</p> <p>3 THE WITNESS: We are saying we're</p> <p>4 making improvements to our existing</p> <p>5 program.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. Okay. And we'll talk about what</p> <p>8 the old program looked like versus what the new</p> <p>9 program looked like. But you are going to start</p> <p>10 doing site visits, right?</p> <p>11 A. Yes.</p> <p>12 Q. You are going to start seeing</p> <p>13 whether they've got lines out the door at the</p> <p>14 pharmacies, right?</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: Again, these are</p> <p>17 things that DEA --</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Could you answer my question</p> <p>20 first?</p> <p>21 A. Yes.</p> <p>22 Q. Okay.</p> <p>23 A. Again, these are things that DEA</p> <p>24 was talking about over time. They were not part</p>	<p style="text-align: right;">Page 161</p> <p>1 got a wide customer base rate?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: I would want them</p> <p>4 to have some program. The details of</p> <p>5 that program can vary, depending on what</p> <p>6 they choose to implement and how</p> <p>7 effective it is.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. So as a manufacturer, you knew</p> <p>10 certainly during your time at Qualitest you just</p> <p>11 couldn't ship it to somebody who was going to</p> <p>12 just put their head in the sand, right?</p> <p>13 MS. VANNI: Objection.</p> <p>14 THE WITNESS: Yes.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. You couldn't ship it to somebody</p> <p>17 who didn't have suspicious order monitoring</p> <p>18 practices right?</p> <p>19 MS. VANNI: Objection.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. That would be a problem?</p> <p>23 MS. VANNI: Objection.</p> <p>24 BY MR. BUCHANAN:</p>

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<p style="text-align: right;">Page 162</p> <p>1 Q. Not a reason --</p> <p>2 A. It could be, yes.</p> <p>3 Q. Not a reasonable thing to do,</p> <p>4 that's for sure, right?</p> <p>5 MS. VANNI: Object to form.</p> <p>6 THE WITNESS: It could be a</p> <p>7 problem.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. And certainly not something a</p> <p>10 responsible company would do or a responsible</p> <p>11 corporate citizen as you've listed here,</p> <p>12 correct?</p> <p>13 MS. VANNI: Object to form.</p> <p>14 THE WITNESS: Again, the company</p> <p>15 is required to abide by the DEA</p> <p>16 regulations. That's the only</p> <p>17 obligations of the company. Because I</p> <p>18 held the company to a different standard</p> <p>19 is not -- it's not what's required by</p> <p>20 the company.</p> <p>21 BY MR. BUCHANAN</p> <p>22 Q. What you said, ma'am, was as</p> <p>23 responsible corporate citizens, we have a</p> <p>24 responsibility to do what you set forth in this</p>	<p style="text-align: right;">Page 164</p> <p>1 your full customer base, correct?</p> <p>2 A. Yes.</p> <p>3 Q. You remember this, right?</p> <p>4 A. I do.</p> <p>5 Q. It was the responsible and right</p> <p>6 thing to do, right?</p> <p>7 A. It was the requirement to</p> <p>8 notify -- not the requirement. It was the</p> <p>9 desire to notify the customer that their orders</p> <p>10 might be held and they might be questioned more</p> <p>11 than -- they might be asked to fill out a</p> <p>12 questionnaire that was different than what they</p> <p>13 had filled out in the past.</p> <p>14 Q. And you were putting them on</p> <p>15 notice that they have a responsibility; they,</p> <p>16 too, have a responsibility --</p> <p>17 A. Yes.</p> <p>18 Q. -- in this system to do all they</p> <p>19 can. That's what you told them, right?</p> <p>20 A. Yes.</p> <p>21 Q. Does this refresh your</p> <p>22 recollection, though, ma'am, that these drugs</p> <p>23 can lead to heart-wrenching problems in our</p> <p>24 communities?</p>
<p style="text-align: right;">Page 163</p> <p>1 letter, correct?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: That is my</p> <p>4 individual belief, yes.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. That was your belief, that was</p> <p>7 Qualitest's belief, as reflected in the letter</p> <p>8 it authorized you to send, correct?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: Depending on the</p> <p>11 approvals, yes.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. Yeah. I mean, this wasn't</p> <p>14 some -- this wasn't some off-the-book thing you</p> <p>15 did, right?</p> <p>16 MS. VANNI: Object to form.</p> <p>17 THE WITNESS: No.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. We're not looking at just a side</p> <p>20 e-mail, you know, my personal view is this,</p> <p>21 right?</p> <p>22 MS. VANNI: Object to form.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. This is a letter that went to</p>	<p style="text-align: right;">Page 165</p> <p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: These drugs</p> <p>3 generally, hydrocodone, oxycodone, yes.</p> <p>4 Again, these drugs did not come from</p> <p>5 Qualitest.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. I don't know what you mean by</p> <p>8 that, ma'am. I don't know what you mean,</p> <p>9 because we've looked at the stat that said</p> <p>10 33 billion, and the schedule that counsel has</p> <p>11 told us is where we go to find out what they</p> <p>12 shipped and the sales of what they've sold of</p> <p>13 these drugs. We've looked where Qualitest sold</p> <p>14 33 billion Vicodins and three-plus billion</p> <p>15 oxycodone, enough to fill medicine cabinets</p> <p>16 throughout this country, many bottles over, and</p> <p>17 you're telling us that that's not your drug</p> <p>18 you're talking about when you write that letter?</p> <p>19 MS. VANNI: Objection.</p> <p>20 THE WITNESS: I'm telling you</p> <p>21 that it's not our drug that's out there</p> <p>22 causing havoc, as you put it.</p> <p>23 We had appropriate controls in</p> <p>24 place. And, again, a shipment -- this</p>

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<p style="text-align: right;">Page 166</p> <p>1 does not mean a sale to a customer.  2 This does not mean a prescription.  3 There are controls in place with  4 DEA. We can't -- we can't receive  5 permission to manufacture these drugs  6 unless there's a proven medical need for  7 the drug.  8 BY MR. BUCHANAN:  9 Q. Yeah, I'm just -- I guess we're  10 just disconnecting because we know -- let's just  11 see if we can get agreement on small parts,  12 okay.  13 We know that Qualitest made  14 30-plus billion, according to the schedules that  15 counsel has pointed us to, Vicodin over a  16 seven-year period of time. You would agree  17 that's what the schedule reflects, correct?  18 MS. VANNI: Object to form.  19 THE WITNESS: I agree, I guess,  20 yes.  21 BY MR. BUCHANAN:  22 Q. You would agree that the schedule  23 reflects that Qualitest, over that seven-year  24 period of time, made some 7 billion-plus pills</p>	<p style="text-align: right;">Page 168</p> <p>1 the Qualitest products in the prior sentence?  2 A. Can be.  3 Q. Right?  4 A. Not are. There's a difference.  5 Q. Oh, we already looked, ma'am, at  6 9 million pills that were unaccounted for in the  7 letter before the last break.  8 Do you recall that?  9 MS. VANNI: Object to form.  10 THE WITNESS: Yes, a  11 recordkeeping error is different than  12 product not being there.  13 BY MR. BUCHANAN:  14 Q. Product not accounted for?  15 A. Not accounted for can also mean  16 that the records did not accurately reflect that  17 quantity.  18 Q. The letter says not accounted for  19 9 million pills, true?  20 MS. VANNI: Object to form.  21 THE WITNESS: Deviations  22 exceeding 9 million tablets in seven of  23 eight of the audited controlled  24 substances.</p>
<p style="text-align: right;">Page 167</p> <p>1 of -- I'm sorry, three-plus billion pills --  2 withdrawn.  3 You would agree over the same  4 seven-year period of time that there were some  5 three-plus billion OxyContin generic equivalents  6 made by Qualitest, correct?  7 MS. VANNI: Object to form.  8 THE WITNESS: If that's the  9 quantity that's here, yes.  10 BY MR. BUCHANAN:  11 Q. Okay. We can agree that your  12 letter which we've marked as Exhibit 5 says a  13 large percentage of your products are  14 characterized as controlled substances? It says  15 that, correct?  16 A. Yes.  17 Q. And I think you told us 70%  18 sounds right to you, right?  19 A. It does.  20 Q. And that these patient -- these  21 products, while necessary for patients, can be  22 targets for abuse and diversion.  23 These products that you are  24 referring to in that sentence is referring to</p>	<p style="text-align: right;">Page 169</p> <p>1 Deviations, a difference from the  2 record versus what's there.  3 BY MR. BUCHANAN:  4 Q. Okay. So what you're recalling,  5 a record that U.S. Attorney is giving you one  6 week to negotiate a fine that is potentially  7 millions of dollars, correct?  8 MS. VANNI: Object to form.  9 THE WITNESS: I don't know what  10 the fine is or was.  11 I'm saying that it's a failure --  12 if you read the first item, failure to  13 maintain --  14 BY MR. BUCHANAN:  15 Q. Just stay with me on my point  16 and -- I'll withdraw the last question, okay, so  17 I don't cut off your answer in fairness to you.  18 So there's not a question pending, I'll ask a  19 fresh one.  20 A. Okay.  21 Q. The next paragraph, ma'am, states  22 that GB -- which we understand to be the  23 subsidiary of Qualitest, correct?  24 A. Generics Bidco.</p>

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<p style="text-align: right;">Page 170</p> <p>1 Q. -- is potentially subject to</p> <p>2 civil penalties that may amount to millions of</p> <p>3 dollars.</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes.</p> <p>6 Q. Millions of dollars' unaccounted</p> <p>7 deviations exceeding 9 million tablets, correct?</p> <p>8 A. The DEA has the capability of</p> <p>9 fining \$10,000 for every recordkeeping</p> <p>10 violation.</p> <p>11 Q. Do you remember what it was?</p> <p>12 A. The violation?</p> <p>13 Q. We talked about this letter</p> <p>14 before, and you said you didn't have a memory of</p> <p>15 it.</p> <p>16 A. I don't, but it says right</p> <p>17 here --</p> <p>18 MS. VANNI: Let him finish his</p> <p>19 question. Go ahead.</p> <p>20 THE WITNESS: Okay.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. You don't have a recollection of</p> <p>23 this event, correct?</p> <p>24 A. Not fully, no.</p>	<p style="text-align: right;">Page 172</p> <p>1 Exhibit No. 6.)</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Passing you what we're marking as</p> <p>4 Exhibit 6 to your deposition, ma'am.</p> <p>5 MR. BUCHANAN: Here you go.</p> <p>6 MS. VANNI: Thanks.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. This follows -- withdrawn.</p> <p>9 Exhibit 6, ma'am, is an e-mail</p> <p>10 exchange with an attachment. The attachment</p> <p>11 appears to be a draft of your "dear valued</p> <p>12 customer" letter. The "dear valued customer"</p> <p>13 letter starts on point 3.</p> <p>14 MR. BUCHANAN: Could you go</p> <p>15 there, Bradley. 586.3. Thanks.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Does that look familiar to you,</p> <p>18 ma'am?</p> <p>19 A. Yes, it does.</p> <p>20 Q. An earlier version of the letter</p> <p>21 that was ultimately sent?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And this is an e-mail from</p> <p>24 you to -- attaching that letter to a handful of</p>
<p style="text-align: right;">Page 171</p> <p>1 Q. Okay. So you don't know whether</p> <p>2 or not there are 9 million tablets unaccounted</p> <p>3 for, whether forms weren't filled out correctly</p> <p>4 or whether it's some combination of both, fair?</p> <p>5 MS. VANNI: Object to form.</p> <p>6 THE WITNESS: No, not fair.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. Okay. Go ahead.</p> <p>9 A. I do know that we had controls in</p> <p>10 place that 9 million tablets would not have</p> <p>11 walked out the door.</p> <p>12 Q. Okay. We do know that you've got</p> <p>13 deviations exceeding 9 million tablets, as noted</p> <p>14 in this notice from the U.S. Attorney that</p> <p>15 followed a DEA inspection that followed a</p> <p>16 conversation with the U.S. Attorney, correct?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. Thank you.</p> <p>21 MR. BUCHANAN: So -- can I have</p> <p>22 586, please. I think this is Exhibit 6.</p> <p>23 (Document marked for</p> <p>24 identification as Par-Norton Deposition</p>	<p style="text-align: right;">Page 173</p> <p>1 people, Mike Reiney, Trey Propst, Margaret</p> <p>2 Richardson and Sandra Parker.</p> <p>3 Do you see that?</p> <p>4 A. Yes, I do.</p> <p>5 Q. And you CC a couple of your</p> <p>6 colleagues, right?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And, first of all, who is</p> <p>9 Mike Reiney?</p> <p>10 A. Mike Reiney is sales.</p> <p>11 Q. Propst?</p> <p>12 A. Also sales.</p> <p>13 Q. Ms. Richardson?</p> <p>14 A. Legal.</p> <p>15 Q. And Sandra Parker?</p> <p>16 A. Also legal.</p> <p>17 Q. Okay. So you had this letter</p> <p>18 that was transmitted to sales and legal, was</p> <p>19 transmitted to them, I think you say, for their</p> <p>20 review, correct?</p> <p>21 A. Yes, it was a -- for the sales</p> <p>22 team, it was a courtesy review, and for legal,</p> <p>23 it was a normal legal review of a document.</p> <p>24 Q. Okay. So the letter that was</p>

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<p style="text-align: right;">Page 174</p> <p>1 ultimately sent by the company, and it looks</p> <p>2 like you are asking for comments if we turn to</p> <p>3 the next page, .2, you are looking for comments</p> <p>4 by, you know, July 23rd.</p> <p>5 Didn't quite happen that fast, I</p> <p>6 guess, that you got it out, right?</p> <p>7 MS. VANNI: Object to form.</p> <p>8 THE WITNESS: Not sure. No, I'm</p> <p>9 not sure when the comments were received</p> <p>10 back, but it didn't go out until</p> <p>11 October. Agreed.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. And you put cautions in your</p> <p>14 transmittal. Well, first of all, you say,</p> <p>15 "Please review the letter, give me comments."</p> <p>16 At a high level, that's what you're saying,</p> <p>17 right?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. So you wanted comments</p> <p>20 from your sales colleagues because this would be</p> <p>21 going to their customers, fair?</p> <p>22 A. Yes.</p> <p>23 Q. And you wanted comments from</p> <p>24 legal because this was a company correspondence,</p>	<p style="text-align: right;">Page 176</p> <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. So you are flagging for them,</p> <p>4 hey, take this seriously, this is an important</p> <p>5 letter, it could add implications, fair?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. And the letter that was</p> <p>10 ultimately revised and sent is the one that we</p> <p>11 looked at in the prior exhibit, correct, ma'am?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. From your perspective</p> <p>14 sitting here today, you endorsed its content,</p> <p>15 correct?</p> <p>16 A. I did.</p> <p>17 Q. And you understood from the</p> <p>18 people who reviewed it they endorsed its content</p> <p>19 as well?</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: Yes.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. You certainly didn't send it out</p> <p>24 on your own without higher-level approval?</p>
<p style="text-align: right;">Page 175</p> <p>1 an official company correspondence?</p> <p>2 A. Correct.</p> <p>3 Q. Okay. The letter is subsequently</p> <p>4 finalized and distributed in the form that we</p> <p>5 looked at earlier, I think it's the prior</p> <p>6 exhibit, Exhibit 5, correct?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And you put cautions in</p> <p>9 there that, you know, this is a letter that's</p> <p>10 going to be going to your customers who may</p> <p>11 further distribute the document to their</p> <p>12 customers, some of whom may even be patients.</p> <p>13 Do you see that?</p> <p>14 A. Yes.</p> <p>15 MS. VANNI: Object to form.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. 586.2?</p> <p>18 A. Yes.</p> <p>19 Q. Then you say "Ultimately the</p> <p>20 letter could also be viewed by competitors or</p> <p>21 regulators, so it's important that the content</p> <p>22 describe what can be expected without providing</p> <p>23 information that may be misinterpreted or</p> <p>24 proprietary."</p>	<p style="text-align: right;">Page 177</p> <p>1 A. I did not.</p> <p>2 Q. What I would like to do is talk</p> <p>3 with you about the meeting with the DEA in March</p> <p>4 of 2013.</p> <p>5 A. Okay.</p> <p>6 MR. BUCHANAN: Can I have,</p> <p>7 please, 1117.</p> <p>8 (Document marked for</p> <p>9 identification as Par-Norton Deposition</p> <p>10 Exhibit No. 7.)</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Passing you, ma'am, what we're</p> <p>13 marking as Exhibit 7 to your deposition.</p> <p>14 MR. BUCHANAN: Do we have a copy</p> <p>15 for counsel? I apologize, Counsel, if</p> <p>16 we get into a subschedule. We may have</p> <p>17 to share the one over there. That's</p> <p>18 unintentional. I'm sure we'll find a</p> <p>19 way to fix that.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Before you, ma'am, is Exhibit 7</p> <p>22 to your deposition.</p> <p>23 Is this a copy of a binder that</p> <p>24 you received at a meeting with the DEA in March</p>

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<p style="text-align: right;">Page 178</p> <p>1 of 2013?</p> <p>2 A. Yes, it is.</p> <p>3 Q. Okay. We were talking about your</p> <p>4 experience at Watson earlier and Anda when you</p> <p>5 went in for that meeting.</p> <p>6 A. Yes.</p> <p>7 Q. Do you recall that?</p> <p>8 A. I do.</p> <p>9 Q. You had a similar binder when you</p> <p>10 went in with them?</p> <p>11 A. I did.</p> <p>12 Q. Okay. This was something the DEA</p> <p>13 was doing from time to time with its</p> <p>14 registrants, fair?</p> <p>15 A. For all distributors, yes.</p> <p>16 Q. There are hundreds and hundreds</p> <p>17 and hundreds of registrants; is that fair?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. There are hundreds and hundreds</p> <p>22 of registrant that are distributors, there are</p> <p>23 hundreds that are manufacturers, fair?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 180</p> <p>1 or couldn't?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: I don't know.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. Okay. All right. So this is the</p> <p>6 binder that you all were given. I guess you</p> <p>7 went in -- you got called in, right?</p> <p>8 MS. VANNI: Object to the form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. This isn't like they just popped</p> <p>12 into Huntsville, Alabama, right?</p> <p>13 A. No.</p> <p>14 Q. And Huntsville is where you were</p> <p>15 at the time?</p> <p>16 A. Yes, it is.</p> <p>17 Q. That was the physical location</p> <p>18 that you called your office every day when you</p> <p>19 went to work?</p> <p>20 A. Yes.</p> <p>21 Q. DEA compliance had an office --</p> <p>22 DEA compliance or Qualitest had an office in</p> <p>23 Huntsville?</p> <p>24 A. Yes, it did, and we also had a</p>
<p style="text-align: right;">Page 179</p> <p>1 Q. And there's, of course,</p> <p>2 prescribers --</p> <p>3 A. Millions of prescribers, yes.</p> <p>4 Q. So but some distributors are</p> <p>5 bigger than others, right?</p> <p>6 A. Yes.</p> <p>7 Q. Some manufacturers are larger</p> <p>8 than others?</p> <p>9 A. Yes.</p> <p>10 Q. Are you aware of other</p> <p>11 manufacturers that made more hydrocodone than</p> <p>12 you?</p> <p>13 MS. VANNI: Object to form.</p> <p>14 THE WITNESS: That would be</p> <p>15 confidential information. I wouldn't</p> <p>16 have access to that.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. You can't figure that out using</p> <p>19 IMS data?</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: I've never looked</p> <p>22 at it for that --</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. You don't know whether you could</p>	<p style="text-align: right;">Page 181</p> <p>1 person in Charlotte.</p> <p>2 Q. Okay. So you get word that</p> <p>3 you're getting called to D.C., right?</p> <p>4 A. Yes.</p> <p>5 MS. VANNI: Object to form.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. You had a sense of what was</p> <p>8 coming?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. You had been through this rodeo</p> <p>13 before?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: I've been to the</p> <p>16 distributor meetings before, yes.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Okay. Apart from the one you</p> <p>19 went to with Anda, had you been to any other</p> <p>20 distributor meetings?</p> <p>21 A. I think I have. I'm not 100%</p> <p>22 sure, but I believe so. I believe I went to one</p> <p>23 for Watson. I'm not sure.</p> <p>24 Q. Okay. Qualitest was both a</p>

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<p style="text-align: right;">Page 182</p> <p>1 manufacturer and a distributor, right?</p> <p>2 A. Yes.</p> <p>3 Q. Had two registrations?</p> <p>4 A. Correct. Well, they had more --</p> <p>5 more than that. We had lab and import-export,</p> <p>6 research.</p> <p>7 Q. They had a distributor</p> <p>8 registration and a manufacturer registration?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. And that's an annual</p> <p>11 process, you've got to renew that?</p> <p>12 A. It is.</p> <p>13 Q. Okay. And every time you renew</p> <p>14 it, you are making a promise you are going to</p> <p>15 abide by the regulation and the statute with</p> <p>16 regard to antidiversion, right?</p> <p>17 MS. VANNI: Objection.</p> <p>18 THE WITNESS: Technically, yes.</p> <p>19 It's not written on there, but yes.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. That is the -- that is the</p> <p>22 implied commitment on the part of the</p> <p>23 registrants, correct?</p> <p>24 MS. VANNI: Objection.</p>	<p style="text-align: right;">Page 184</p> <p>1 A. To a certain extent, yes. Yes.</p> <p>2 Q. For example, if you go to 1117.4,</p> <p>3 they start to tell you about the statute that</p> <p>4 you operate under, right?</p> <p>5 A. Yes.</p> <p>6 Q. The Comprehensive Drug Abuse</p> <p>7 Prevention and Control Act as amended created a</p> <p>8 system for the legitimate manufacturing,</p> <p>9 distribution and prescribing dispensing of</p> <p>10 controlled substances.</p> <p>11 The next bullet states, "Each</p> <p>12 registrant within the closed system of</p> <p>13 distribution has defined privileges and</p> <p>14 responsibilities in which they must operate."</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. And you had that understanding,</p> <p>18 correct?</p> <p>19 A. I did.</p> <p>20 Q. And you didn't need the DEA to</p> <p>21 tell you that, correct?</p> <p>22 A. Not at that point, no.</p> <p>23 Q. In fact, you had been working in</p> <p>24 this framework for 20 years at that point,</p>
<p style="text-align: right;">Page 183</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. I'm asking for permission to make</p> <p>4 controlled substances, I will abide by the</p> <p>5 statute, I will abide by the regulations.</p> <p>6 That's part of the process, correct?</p> <p>7 MS. VANNI: Object to form.</p> <p>8 THE WITNESS: Yes, it is.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. I would like to direct you to</p> <p>11 hopefully pages your counsel has.</p> <p>12 And I guess let's set the table a</p> <p>13 little bit with what happened that day.</p> <p>14 So you go up in person, you went</p> <p>15 with a few other folks from Qualitest?</p> <p>16 A. I was -- I believe there was a</p> <p>17 snowstorm, and we did go with -- there were</p> <p>18 other people that were going to be in the room</p> <p>19 that didn't make it in, but there was at least</p> <p>20 one other person, I believe, with me.</p> <p>21 Q. Okay. So you go in, and the DEA</p> <p>22 starts to give you the presentation, I guess,</p> <p>23 that you've heard before, certainly the general</p> <p>24 portion of it, correct?</p>	<p style="text-align: right;">Page 185</p> <p>1 right?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. When a registrant -- next</p> <p>4 slide, the bottom, "When a registrant fails to</p> <p>5 adhere to their responsibilities, those</p> <p>6 violations represent a danger to the public and</p> <p>7 jeopardize the closed system of distribution."</p> <p>8 Do you see that?</p> <p>9 A. I do.</p> <p>10 Q. Do you agree with that?</p> <p>11 A. Yes.</p> <p>12 Q. And, again, this is on the slide</p> <p>13 that says closed system, something you</p> <p>14 understood as of that point in time, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And something that you echoed to</p> <p>17 your customers when you wrote a letter out to</p> <p>18 them, correct?</p> <p>19 A. Correct.</p> <p>20 Q. To the extent others didn't know</p> <p>21 it, you were telling them the same thing, right?</p> <p>22 A. Yes.</p> <p>23 Q. We all have a responsibility,</p> <p>24 correct?</p>

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<p style="text-align: right;">Page 186</p> <p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: Yes, that's what I</p> <p>3 was telling them.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. And that's the regulatory</p> <p>6 framework that we were just talking about, and</p> <p>7 then there's also -- excuse me, that's the</p> <p>8 statutory framework, right?</p> <p>9 A. Mm-hmm.</p> <p>10 Q. And then we go forward to</p> <p>11 suspicious orders, there's a particular</p> <p>12 regulation specific to suspicious orders,</p> <p>13 correct?</p> <p>14 A. 130174.</p> <p>15 Q. Great. We'll go to 1117.9.</p> <p>16 And that regulation requires</p> <p>17 that -- and it says "suspicious orders" on the</p> <p>18 side. I'm sorry, the one at the bottom.</p> <p>19 MR. BUCHANAN: Thank you,</p> <p>20 Bradley. Since there's a few documents</p> <p>21 on the table, I'll try to keep you in</p> <p>22 sync.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. The heading on the side is</p>	<p style="text-align: right;">Page 188</p> <p>1 and it elucidates us further with your due</p> <p>2 diligence responsibility on E 1117.11. "Due</p> <p>3 diligence" know your customers.</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. "Prior to filing an order, the</p> <p>7 distribute should review the following: Unusual</p> <p>8 frequency of orders, unusual size of orders,</p> <p>9 deviating substantially from a normal pattern,"</p> <p>10 and then it lists the regulation there.</p> <p>11 You see that?</p> <p>12 A. Yes.</p> <p>13 Q. And then it continues with due</p> <p>14 diligence below, "Range of products being</p> <p>15 purchased, methods of payment (cash, insurance,</p> <p>16 Medicaid), locations and hours of operation,</p> <p>17 percent controlled versus percent noncontrolled,</p> <p>18 customer pickup at distributorship."</p> <p>19 Do you see that?</p> <p>20 A. Yes, I do.</p> <p>21 Q. "Other aspects of due diligence,"</p> <p>22 correct?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 THE WITNESS: Other guidances</p>
<p style="text-align: right;">Page 187</p> <p>1 "Suspicious Orders." The regulation you just</p> <p>2 stated from memory, ma'am, is listed on the</p> <p>3 slide, right?</p> <p>4 A. Yes.</p> <p>5 Q. A regulation you've known about</p> <p>6 for a long time, right?</p> <p>7 A. Yes.</p> <p>8 Q. I mean, you've known about that</p> <p>9 regulation because that's been around since</p> <p>10 before your time at Ciba-Geigy?</p> <p>11 A. Correct.</p> <p>12 Q. And you've heard about that</p> <p>13 regulation at distributor conferences and</p> <p>14 manufacturer conferences, correct?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. 21 CFR 1301.74 requires</p> <p>17 that registrants design and operate a system to</p> <p>18 identify suspicious orders.</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. "Report suspicious orders to</p> <p>22 DEA," what does it say?</p> <p>23 A. "When discovered."</p> <p>24 Q. Okay. And then it goes through</p>	<p style="text-align: right;">Page 189</p> <p>1 from DEA as to what to look at.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Right.</p> <p>4 I mean, look, the DEA doesn't --</p> <p>5 and the FDA doesn't tell you how to promote your</p> <p>6 drug to make the most sales, right? Companies</p> <p>7 figure that out on their own, right?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: They do tell you</p> <p>10 how to promote your drug and how not to</p> <p>11 promote.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. They tell you how you can't do</p> <p>14 it?</p> <p>15 A. Yes.</p> <p>16 Q. I mean, companies are pretty</p> <p>17 crafty when it comes to figuring out marketing</p> <p>18 that can be effective, to figure out educational</p> <p>19 seminars that might educate physicians depending</p> <p>20 on how you determine the word "educate" and</p> <p>21 other ways to grow a market for their product.</p> <p>22 There's marketing departments that are built to</p> <p>23 do those types of things, fair?</p> <p>24 MS. VANNI: Object to form.</p>

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<p style="text-align: right;">Page 190</p> <p>1 THE WITNESS: Yes, but I think</p> <p>2 it's a little bit different.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. You agree that as it relates to</p> <p>5 marketing and promotion, companies have</p> <p>6 departments built to do that, right?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. There's also a regulation</p> <p>9 that says that if you're going to seek our</p> <p>10 permission -- or a statute that says if you are</p> <p>11 going to seek permission to operate in this</p> <p>12 closed system that you have to have effective</p> <p>13 controls against diversion, right?</p> <p>14 A. Yes.</p> <p>15 Q. And companies certainly can, as</p> <p>16 you have from time to time done, can employ</p> <p>17 their own tools and techniques to maintain</p> <p>18 effective controls against diversion, right?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. There are minimum ways to do it</p> <p>23 and there's a suspicious order monitoring</p> <p>24 regulation that says something about that,</p>	<p style="text-align: right;">Page 192</p> <p>1 was let go.</p> <p>2 Q. Okay. Two people who had the</p> <p>3 title of DEA compliance, or at least under that</p> <p>4 umbrella, to maintain effective controls against</p> <p>5 diversion?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: Yes. However, it's</p> <p>8 not -- it's not just those two people's</p> <p>9 responsibility.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. It should go --</p> <p>12 A. That's why we train -- yeah.</p> <p>13 Q. It should go throughout the</p> <p>14 organization, that responsibility, right?</p> <p>15 A. Correct.</p> <p>16 Q. And that was one of the things in</p> <p>17 2013 after you had this meeting that you set out</p> <p>18 to implement, correct?</p> <p>19 A. To enhance.</p> <p>20 Q. Okay. And we'll talk about what</p> <p>21 it was before versus what it was later?</p> <p>22 A. Yes.</p> <p>23 Q. Because ultimately it's a</p> <p>24 company-wide obligation to maintain effective</p>
<p style="text-align: right;">Page 191</p> <p>1 correct?</p> <p>2 A. Correct.</p> <p>3 Q. But ultimately the manufacturers</p> <p>4 and distributors have a statutory obligation to</p> <p>5 maintain effective controls against diversion,</p> <p>6 correct?</p> <p>7 MS. VANNI: Object to form.</p> <p>8 THE WITNESS: Yes.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Would it be fair to say, ma'am,</p> <p>11 in the time that you've spent at Qualitest, the</p> <p>12 group that handled -- would you say the</p> <p>13 marketing group was bigger than the DEA</p> <p>14 compliance group?</p> <p>15 A. Actually, no.</p> <p>16 Q. The sales group?</p> <p>17 A. Oh, I don't know. I don't know</p> <p>18 about out in the field. Maybe, but I don't</p> <p>19 know.</p> <p>20 Q. Because in your DEA compliance</p> <p>21 group before you brought in the people you</p> <p>22 brought in, when you started there, how many</p> <p>23 people were in DEA compliance?</p> <p>24 A. There were two and the one that</p>	<p style="text-align: right;">Page 193</p> <p>1 controls against diversion, correct?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: Just like it's a</p> <p>4 company-wide obligation to make your</p> <p>5 product safe and effective.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. Right, right.</p> <p>8 Because if you're making</p> <p>9 controlled substances, you've made that</p> <p>10 commitment, you've made that commitment to get</p> <p>11 the permission slip to make the drug that you're</p> <p>12 going to maintain effective controls against</p> <p>13 diversion, fair?</p> <p>14 A. The quota, yes.</p> <p>15 MS. VANNI: Object to form.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Right?</p> <p>18 So as a company, the company must</p> <p>19 be committed to maintain effective controls</p> <p>20 against diversion, right?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: The company</p> <p>23 can't -- the individuals at the company</p> <p>24 are not -- they're not experienced in</p>

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<p style="text-align: right;">Page 194</p> <p>1 a -- what gets diverted and what doesn't</p> <p>2 or in additional controls that they can</p> <p>3 put in place.</p> <p>4 We learn that from DEA. We learn</p> <p>5 that from the guidances and from the</p> <p>6 presentations that they give. We're</p> <p>7 not -- most people in the company are</p> <p>8 not -- they don't have law enforcement</p> <p>9 backgrounds, they don't have medical</p> <p>10 backgrounds.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Right.</p> <p>13 So education is an important</p> <p>14 component?</p> <p>15 A. It is, from DEA, yes.</p> <p>16 Q. Within a company certainly,</p> <p>17 right?</p> <p>18 A. Yes.</p> <p>19 Q. Within a company, a company has</p> <p>20 got to educate its employees company-wide on how</p> <p>21 to maintain effective controls against</p> <p>22 diversion, right?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 THE WITNESS: To abide by the DEA</p>	<p style="text-align: right;">Page 196</p> <p>1 Q. Okay. We see the DEA showing</p> <p>2 examples on 1117.12 of kind of -- it's not the</p> <p>3 best picture, but you've probably seen this</p> <p>4 picture a few times, haven't you?</p> <p>5 A. Yes.</p> <p>6 Q. It's shown up in DEA</p> <p>7 presentations and other presentations?</p> <p>8 A. Yes, it has.</p> <p>9 Q. It's representing really what you</p> <p>10 can see when you actually go and see your</p> <p>11 customer, right?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. Something that you could see in a</p> <p>15 customer, right?</p> <p>16 A. Potentially.</p> <p>17 Q. Right, lines --</p> <p>18 A. Hopefully not.</p> <p>19 Q. -- people sitting on the floor --</p> <p>20 I mean, would it surprise you to know that you</p> <p>21 had customers like this?</p> <p>22 MS. VANNI: Object to form.</p> <p>23 THE WITNESS: I would be</p> <p>24 surprised in -- from a Qualitest</p>
<p style="text-align: right;">Page 195</p> <p>1 regulations, yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. And if you're going to -- if</p> <p>4 you're going to sell controlled substances and</p> <p>5 if you are going to make the promise to the</p> <p>6 government that you're going to maintain</p> <p>7 effective controls against the government, you</p> <p>8 certainly should, right?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: Do training.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. You certainly -- if you are</p> <p>13 saying you are going to maintain effective</p> <p>14 controls against diversion to get that</p> <p>15 registration, you would agree that you certainly</p> <p>16 should implement effective controls to prevent</p> <p>17 diversion, fair?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. That's -- that's the promise,</p> <p>22 right?</p> <p>23 A. Yes, it's a privilege to have a</p> <p>24 license.</p>	<p style="text-align: right;">Page 197</p> <p>1 perspective, yes, I would be very</p> <p>2 surprised.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. Well, Qualitest had direct</p> <p>5 pharmacy customers, correct?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. Do you recall that?</p> <p>9 A. I don't believe so.</p> <p>10 Q. Okay. Maybe we'll have a chance</p> <p>11 to talk about that at risk of going down too</p> <p>12 many different forks in the road to actually get</p> <p>13 there, but hopefully we'll have a chance.</p> <p>14 So these are the types of things</p> <p>15 that the DEA is saying to look for. A lot of</p> <p>16 cash transactions, right? Why could that be a</p> <p>17 sign? Has that been associated with illicit use</p> <p>18 of drugs?</p> <p>19 A. That's what DEA says, yes --</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: There's no</p> <p>22 traceability.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Right.</p>

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<p style="text-align: right;">Page 198</p> <p>1 And, I mean, the use of cash for 2 drugs was not something that was new in 2011, 3 right? 4 MS. VANNI: Object to form. 5 THE WITNESS: Yeah, should not 6 happen. 7 BY MR. BUCHANAN: 8 Q. No, that shouldn't happen. 9 That's kind of a commonsense thing, right? 10 A. Yes. 11 Q. If a pharmacy or a customer is 12 doing, you know, 70, 80% of their business or 13 50% of their business in controlled substances, 14 and the national average is 13%, that might be 15 something of a red flag, right? 16 A. It would be something -- 17 MS. VANNI: Object to form. 18 THE WITNESS: -- to look into 19 further, yes. 20 BY MR. BUCHANAN: 21 Q. Right. 22 If the pharmacy itself has the 23 cage, no front-end merchandise, that would be 24 something to consider, right?</p>	<p style="text-align: right;">Page 200</p> <p>1 things like this. 2 MR. BUCHANAN: And I'm sorry, 3 Counsel, this one is not in yours. I 4 can see it. We're not going to 5 substantively discuss it. 6 BY MR. BUCHANAN: 7 Q. They sent you a decision from the 8 Supreme Court from 1943, right, Direct Sales 9 versus United States? 10 A. Mm-hmm. 11 Q. And they brought a series of 12 cases and regulatory actions to your attention 13 about the types of things that are really 14 problematic and what you got to be doing and 15 what to watch out for, right? 16 MS. VANNI: Object to form. 17 THE WITNESS: They very much 18 skimmed over the cases. They didn't go 19 into them in a lot of detail, but they 20 were presented, yes. 21 BY MR. BUCHANAN: 22 Q. Right. 23 And I suppose if you were not a 24 person who was generally reading that kind of</p>
<p style="text-align: right;">Page 199</p> <p>1 A. It would be. 2 Q. Something that you can see when 3 you go and do the due diligence on your 4 customers, right? 5 A. Yes. 6 Q. I think you talked about Watson 7 actually is a manufacturer starting to implement 8 customer visits as part of their SOM program at 9 your urging, I can't remember whether you were 10 instrumental or what word you used in your 11 summary, but at your urging, essentially, before 12 you left in 2009, true? 13 MS. LEIBELL: Object to form. 14 THE WITNESS: We did talk about 15 it obviously, yes. 16 BY MR. BUCHANAN: 17 Q. And then we got to the meat of 18 the -- they sent you a bunch of decisions? 19 A. Yes. 20 Q. Probably some that you learned 21 about in your pharmacy classes in Florida, 22 right? 23 A. And I had a practice of reading 24 the Federal Registers or skimming them for</p>	<p style="text-align: right;">Page 201</p> <p>1 thing, maybe somebody else on your team or maybe 2 from another manufacturer, they may have found 3 that new and enlightened, but you are saying you 4 were aware of this already? 5 MS. VANNI: Object to form. 6 THE WITNESS: Not all of them, 7 but some of them, yes. 8 BY MR. BUCHANAN: 9 Q. Okay. And then towards the back, 10 in kind of more the meat of this is a series of 11 charts. 12 Can you pull up so counsel can 13 see it, I don't want to talk about it if she 14 can't see it, 1117.232. And it's on your screen 15 as well, ma'am. 16 Do you recall the DEA presenting 17 charts like these to you at this meeting in 18 2011? 19 A. I do. 20 Q. Do you recall the DEA presenting 21 charts like these to you when you were with Anda 22 in 2008 or '9? 23 A. I do. 24 MS. KOSKI: Object to form.</p>

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<p style="text-align: right;">Page 202</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. That was -- the DEA was</p> <p>3 presenting to the various distributors and</p> <p>4 manufacturers when it got to them information</p> <p>5 concerning what they saw about their</p> <p>6 customers -- about their sale transactions,</p> <p>7 correct?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: And their</p> <p>10 customer's customer.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Thank you. I'm going to get</p> <p>13 there. You don't have to anticipate it for me,</p> <p>14 though.</p> <p>15 A. Okay.</p> <p>16 Q. They were presenting, first of</p> <p>17 all, your volume -- "your" meaning Qualitest's</p> <p>18 volume of this particular dosage of oxycodone,</p> <p>19 we're at 1117.232, and those two companies there</p> <p>20 under Alabama Vintage Pharmaceuticals and</p> <p>21 Generics Bidco, those are both Qualitest</p> <p>22 affiliates, correct?</p> <p>23 A. Yes.</p> <p>24 Q. They were their registrants that</p>	<p style="text-align: right;">Page 204</p> <p>1 Q. Also distributors, right?</p> <p>2 A. Yes.</p> <p>3 Q. So we see distributors that were</p> <p>4 traced to your production and we see end</p> <p>5 pharmacies that were traced to the production in</p> <p>6 the charts that the DEA gave you that day, fair?</p> <p>7 MS. VANNI: Object to form.</p> <p>8 THE WITNESS: Yes.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Okay. And the DEA, as part of</p> <p>11 this, said you're not doing enough, right?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: Not necessarily,</p> <p>14 no. No, they did not say that.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. They said your system was</p> <p>17 inadequate?</p> <p>18 A. They said that we want you to be</p> <p>19 aware, we're having these meetings so that</p> <p>20 you're aware of where your product is going</p> <p>21 further down the supply chain, and we want to</p> <p>22 work with you to basically help prevent the</p> <p>23 product from getting into the wrong hands, and</p> <p>24 we're asking you and all other distributors to</p>
<p style="text-align: right;">Page 203</p> <p>1 manufactured or distributed Qualitest products,</p> <p>2 right?</p> <p>3 A. I believe the first one is the</p> <p>4 manufacturer and the second is the distributor.</p> <p>5 Q. Right.</p> <p>6 So we have, you know, some</p> <p>7 100-plus million pills of oxycodone</p> <p>8 15 milligrams in hundred-count bottles, that's</p> <p>9 what's reflected on this sheet, right?</p> <p>10 MS. VANNI: Object to form.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. And then as you go through the</p> <p>14 sheets, you can see that the DEA presented to</p> <p>15 you other dosages, you know, 30-milligram</p> <p>16 tablets, other bottle counts, and they were</p> <p>17 calling out to you what you were reporting to</p> <p>18 the DEA and they were also calling out to you</p> <p>19 information they were learning about the end</p> <p>20 recipient of your product in terms of the</p> <p>21 pharmacies, correct?</p> <p>22 MS. VANNI: Object to form.</p> <p>23 THE WITNESS: Correct.</p> <p>24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 205</p> <p>1 see if you can make improvements to help -- to</p> <p>2 help make sure the product stays within the</p> <p>3 closed loop.</p> <p>4 MR. BUCHANAN: Can I have Exhibit</p> <p>5 575, please. How are we doing as a time</p> <p>6 check? How long have we been going?</p> <p>7 THE VIDEOGRAPHER: Two hours, 40</p> <p>8 minutes, approximately.</p> <p>9 MR. BUCHANAN: Let me just mark</p> <p>10 this document and I'll take a short</p> <p>11 break. I don't know how long we've been</p> <p>12 going. I lost track.</p> <p>13 MS. VANNI: I lost track, too.</p> <p>14 It's quarter to 12.</p> <p>15 MR. BUCHANAN: Can we just mark</p> <p>16 this one real quick just so your counsel</p> <p>17 has it.</p> <p>18 THE WITNESS: Yeah.</p> <p>19 MR. BUCHANAN: It will include</p> <p>20 the schedules.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Ma'am, while we're waiting for</p> <p>23 that, we'll talk more about your interactions</p> <p>24 with DEA that day, what they told you about your</p>



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<p style="text-align: right;">Page 206</p> <p>1 systems and your self-assessment of the</p> <p>2 inadequacies in your SOM system at that point in</p> <p>3 time.</p> <p>4 Do you have a recollection,</p> <p>5 though, that in your eyes, Qualitest SOM</p> <p>6 practices at that point in time, as of the time</p> <p>7 of the DEA meeting, were inadequate?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: I would not say</p> <p>10 that they were inadequate. I would say</p> <p>11 that we needed to make improvements, and</p> <p>12 I would have come back and presented it</p> <p>13 in a way that -- you know, there's a lot</p> <p>14 going on at a pharmaceutical company and</p> <p>15 for -- for this to -- for any</p> <p>16 improvements that I wanted to make to</p> <p>17 get the right -- to basically -- what --</p> <p>18 to get the attention that it needed, you</p> <p>19 have to make things a little more urgent</p> <p>20 than they may actually be, so I'm sure</p> <p>21 you'll see that in my -- in my e-mails.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. Getting management buy-in can be</p> <p>24 a challenge at a pharmaceutical company?</p>	<p style="text-align: right;">Page 208</p> <p>1 what you told your customers is that as a</p> <p>2 responsible company, you had the obligation to</p> <p>3 do what was in your letter, and they had the</p> <p>4 same obligation, that's what you told your</p> <p>5 customers, right?</p> <p>6 A. The customers, yes. The</p> <p>7 customers needed a heads-up to -- needed</p> <p>8 education on what was changing.</p> <p>9 (Document marked for</p> <p>10 identification as Par-Norton Deposition</p> <p>11 Exhibit No. 8.)</p> <p>12 MR. BUCHANAN: I'm passing you,</p> <p>13 ma'am, what we're marking as Exhibit 8</p> <p>14 to your deposition. There we go.</p> <p>15 MS. VANNI: Thanks.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. And this is really more for the</p> <p>18 benefit of counsel so they have the charts that</p> <p>19 I was referring to.</p> <p>20 After you got back from the</p> <p>21 meeting -- this is March 6, 5:58 p m., you tore</p> <p>22 off the schedules and you sent them around</p> <p>23 within the company, right?</p> <p>24 MS. VANNI: Object to form.</p>
<p style="text-align: right;">Page 207</p> <p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: Not so much -- not</p> <p>3 so much getting their buy-in, but making</p> <p>4 them aware of the urgency surrounding</p> <p>5 it, that it's not just, you know, Tracey</p> <p>6 wants to make improvements. That</p> <p>7 there's an impact to making improvements</p> <p>8 and that there's things that -- you</p> <p>9 know, things that we can do better.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Right.</p> <p>12 I mean, when you're talking about</p> <p>13 controlled substances and the heart-wrenching</p> <p>14 havoc that they can wreak in the communities,</p> <p>15 responsible companies act to try and minimize</p> <p>16 that risk by maintaining effective controls</p> <p>17 against diversion, you agree?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: I think the company</p> <p>20 has to follow the DEA regulations, and</p> <p>21 if you do that, then ultimately you will</p> <p>22 be preventing that from happening.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. And what you wrote certainly and</p>	<p style="text-align: right;">Page 209</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. And what you're doing is -- who</p> <p>4 is Peter Bigelow, by the way?</p> <p>5 A. He was actually -- at one point,</p> <p>6 he was my supervisor, but he was actually</p> <p>7 over -- I think he was over Denise and Sanjay at</p> <p>8 the time.</p> <p>9 Q. Senior vice president?</p> <p>10 A. Sanjay was my supervisor.</p> <p>11 Q. Okay. Senior vice president?</p> <p>12 A. Yes.</p> <p>13 Q. Yes, okay.</p> <p>14 And what was his -- you know,</p> <p>15 senior vice president for sales, drug safety?</p> <p>16 A. No.</p> <p>17 MS. VANNI: Objection.</p> <p>18 THE WITNESS: He was kind of like</p> <p>19 over the COO, I guess. He was</p> <p>20 contract -- I think he was a contractor</p> <p>21 that was brought in, so he was kind of</p> <p>22 assisting the plant manager.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Okay.</p>



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<p style="text-align: right;">Page 210</p> <p>1 A. He had a couple of different</p> <p>2 roles, I believe, while he was there.</p> <p>3 Q. Senior person?</p> <p>4 A. Yes. Senior person.</p> <p>5 Q. Senior to your immediate boss?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Senior to the chief</p> <p>8 operating officer?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. All right. So you get</p> <p>11 back, you tear off the schedules and you send</p> <p>12 them up the corporate ladder to a senior vice</p> <p>13 president, fair?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: Mm-hmm.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Okay. And you say, "Attached are</p> <p>18 the charts that the DEA reviewed with us at the</p> <p>19 meeting today."</p> <p>20 And then you say, "As we</p> <p>21 expected," and then you describe them, right?</p> <p>22 A. Yes.</p> <p>23 Q. And so this was not news to you?</p> <p>24 MS. VANNI: Object to form.</p>	<p style="text-align: right;">Page 212</p> <p>1 A. If they allowed it.</p> <p>2 Q. And if they didn't, you don't</p> <p>3 have to do business with them?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 THE WITNESS: Yes, correct.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. Because ultimately, to secure the</p> <p>8 supply chain, to ensure that everyone views</p> <p>9 things the way you did, the way Qualitest did,</p> <p>10 to maintain effective controls against</p> <p>11 diversion, we have to do everything we can to</p> <p>12 ensure that your customers felt the same way,</p> <p>13 you could just not sell it to them if they</p> <p>14 wouldn't give you the information, right?</p> <p>15 MS. VANNI: Objection.</p> <p>16 THE WITNESS: We could.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. And there's no obligation for you</p> <p>19 to sell to people, right?</p> <p>20 MS. VANNI: Objection.</p> <p>21 THE WITNESS: Correct.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. It's a choice?</p> <p>24 MS. VANNI: Objection.</p>
<p style="text-align: right;">Page 211</p> <p>1 THE WITNESS: No, having attended</p> <p>2 other distributor initiatives, it was</p> <p>3 not news.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. Right, that not only are you</p> <p>6 supposed to look at your customers, but also</p> <p>7 your customers' customers, right?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: When you can, when</p> <p>10 you have the information to do so.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. And when you can generate it,</p> <p>13 right?</p> <p>14 A. To my knowledge at that time, we</p> <p>15 didn't have that capability, but yes.</p> <p>16 Q. But certainly you had the ability</p> <p>17 for any of your customers to say, hey, I'm going</p> <p>18 to stop by today?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: To our customers?</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Sure.</p> <p>23 A. Yeah.</p> <p>24 Q. Right, I mean, you can --</p>	<p style="text-align: right;">Page 213</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. And so to get information about</p> <p>4 your customers, you can do this, you can send</p> <p>5 letters and ask for information back, as you did</p> <p>6 in October of 2013, correct?</p> <p>7 A. Yes.</p> <p>8 Q. And let's just be clear, is that</p> <p>9 the first time that Qualitest ever sent a</p> <p>10 request to any of its customers for their SOM</p> <p>11 program?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: I don't know. It</p> <p>14 was the first time during my tenure that</p> <p>15 we asked for something and called it</p> <p>16 SOMs-related, so there is other</p> <p>17 information that's gathered about</p> <p>18 customers as well.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. Is it the first time that you can</p> <p>21 remember as a systemic matter that you asked for</p> <p>22 the assurance from all of your customers that</p> <p>23 they had SOM programs and that you talked about</p> <p>24 potentially coming out and seeing their</p>

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<p style="text-align: right;">Page 214</p> <p>1 facilities?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: SOM programs, yes.</p> <p>4 Seeing their facilities, no. There were</p> <p>5 others that did visit customers. It</p> <p>6 might not have been called a SOMs visit,</p> <p>7 but it did satisfy, you know, most of --</p> <p>8 most or all of the requirements.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Right.</p> <p>11 So as you're saying -- I'm</p> <p>12 hearing what you're saying is you made it a DEA</p> <p>13 compliance matter in October of 2013?</p> <p>14 A. Yes.</p> <p>15 Q. As of October 2013, DEA</p> <p>16 compliance implemented a SOM program and then</p> <p>17 memorialized it with SOPs and formalized it with</p> <p>18 some activity to --</p> <p>19 A. We -- I'm sorry, go ahead.</p> <p>20 Q. -- to formally implement a know</p> <p>21 your customer and know your customers' customer</p> <p>22 program, fair?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 THE WITNESS: No, not fair. We</p>	<p style="text-align: right;">Page 216</p> <p>1 March of 2013, you got the call, come to DC?</p> <p>2 A. Mm-hmm.</p> <p>3 Q. DEA wants to have a chat with</p> <p>4 you, right?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. DEA gives you the binder,</p> <p>7 I think it's still under your hand.</p> <p>8 A. It is.</p> <p>9 Q. A binder like that which you</p> <p>10 received from Anda several years before,</p> <p>11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. The Anda binder obviously had --</p> <p>14 MS. KOSKI: Objection.</p> <p>15 MR. BUCHANAN: Every Anda</p> <p>16 objection is presumably coming from --</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. And they gave you a binder that</p> <p>19 also contained information about Anda's business</p> <p>20 and Anda's customers, correct?</p> <p>21 A. Correct.</p> <p>22 Q. Okay. And we looked at an e-mail</p> <p>23 that you sent, a separate e-mail, where you</p> <p>24 forwarded the schedules upstream to a senior</p>
<p style="text-align: right;">Page 215</p> <p>1 improved upon the existing program.</p> <p>2 MR. BUCHANAN: It's as good a</p> <p>3 time as any for a break.</p> <p>4 MS. VANNI: It's 10 of 12. You</p> <p>5 want to take a lunch break? What do you</p> <p>6 want to do?</p> <p>7 THE VIDEOGRAPHER: Let's go off</p> <p>8 the record. The time is 11:51 a.m.</p> <p>9 (Luncheon recess.)</p> <p>10 (Document marked for</p> <p>11 identification as Par-Norton Deposition</p> <p>12 Exhibit No. 9.)</p> <p>13 THE VIDEOGRAPHER: We're now</p> <p>14 going back on the record. The time is</p> <p>15 12:45 p.m.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Good afternoon, Ms. Norton.</p> <p>18 After lunch but you're still under oath, you're</p> <p>19 good?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Passing you what we're</p> <p>22 marking as Exhibit 9 to your deposition. We</p> <p>23 were talking, just to reorient you before the</p> <p>24 break, we were looking at that period of time in</p>	<p style="text-align: right;">Page 217</p> <p>1 vice president at Qualitest at the time for his</p> <p>2 information, and you noted that, as we expected,</p> <p>3 we were at the DEA, they gave us this stuff on</p> <p>4 our customers, right?</p> <p>5 MS. VANNI: Object to form.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. Okay. All right. So here's more</p> <p>9 of a -- if you will, a bullet point summary you</p> <p>10 sent around to some other people in the group?</p> <p>11 A. Mm-hmm.</p> <p>12 Q. Not to the senior vice president.</p> <p>13 This is -- looks like more your working group on</p> <p>14 compliance issues and DEA stuff?</p> <p>15 A. It's my boss, my boss's boss and</p> <p>16 then his boss.</p> <p>17 Q. Okay. We're looking at Exhibit</p> <p>18 657 from March 7, 2013, and I'm a little</p> <p>19 confused on my dates here. Is this the same day</p> <p>20 as the meeting or the next day? You have the</p> <p>21 binder right before you?</p> <p>22 A. This is March 7th versus this is</p> <p>23 the day after the meeting.</p> <p>24 Q. Got you. Okay. So March 7th,</p>

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<p style="text-align: right;">Page 218</p> <p>1 the next night you're 5:00, I guess late</p> <p>2 afternoon, you're sending around your notes, and</p> <p>3 you note that you were not really in a position</p> <p>4 to be taking the notes yourself. You were kind</p> <p>5 of doing your best to be engaged with the DEA</p> <p>6 when they were talking to you, right?</p> <p>7 A. Yes, to listen.</p> <p>8 Q. Okay. So this is kind of your</p> <p>9 notes after you reflected on it and you just had</p> <p>10 a day and you kind of noted down some takeaways,</p> <p>11 fair?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Okay. If we scroll down and we</p> <p>16 looked at a chart of the production of the</p> <p>17 company's -- I don't know the number of pills,</p> <p>18 hydrocodone and oxycodone that were made over</p> <p>19 the years.</p> <p>20 Do you recall us looking at that</p> <p>21 chart earlier today?</p> <p>22 A. I recall looking at it, yes.</p> <p>23 Q. Yeah, and when I say the chart, I</p> <p>24 mean the one that we generated from the</p>	<p style="text-align: right;">Page 220</p> <p>1 Q. And then what did they say about</p> <p>2 prescription abuse?</p> <p>3 A. "Prescription abuse of these two</p> <p>4 items is worse than addiction to heroin and</p> <p>5 cocaine."</p> <p>6 Q. Okay. And that was true, to your</p> <p>7 knowledge, at that point in time, right?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: That's really</p> <p>10 something that I wouldn't know. I was,</p> <p>11 you know, getting that from DEA.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. I mean, you weren't following the</p> <p>14 public discussion and the congressional hearings</p> <p>15 and everything that was going on really outside</p> <p>16 the walls of Qualitest with regard to the</p> <p>17 epidemic of opioid abuse?</p> <p>18 MS. VANNI: Objection.</p> <p>19 THE WITNESS: I couldn't put a</p> <p>20 number on it or compare it to heroin or</p> <p>21 cocaine without the details coming from</p> <p>22 DEA.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Okay. Suffice it to say, without</p>
<p style="text-align: right;">Page 219</p> <p>1 spreadsheets counsel told us to look at.</p> <p>2 A. Yes.</p> <p>3 Q. And that's where we got the</p> <p>4 33 million tablets of the Vicodin generic</p> <p>5 equivalent, and we got the 3 plus million</p> <p>6 tablets of oxycodone.</p> <p>7 Do you recall that discussion?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And so what you heard was</p> <p>10 that these products, the one identified in the</p> <p>11 first bullet, hydrocodone and oxycodone products</p> <p>12 are being abused and diverted, right?</p> <p>13 MS. VANNI: Object to form.</p> <p>14 MR. BUCHANAN: Could you</p> <p>15 highlight, please, the first bullet.</p> <p>16 THE WITNESS: It says DEA is</p> <p>17 looking at top manufacturers of</p> <p>18 hydrocodone and oxycodone.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. That's right. And then we go to</p> <p>21 the third bullet, and they say, "these products</p> <p>22 are being abused and diverted."</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 221</p> <p>1 the DEA telling you that, you still knew it was</p> <p>2 a big problem at that point in time? You knew</p> <p>3 there were congressional hearings going on,</p> <p>4 right?</p> <p>5 MS. VANNI: Objection.</p> <p>6 THE WITNESS: I knew that</p> <p>7 hydrocodone and oxycodone was being</p> <p>8 abused.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Okay. You knew that they were</p> <p>11 also being diverted, right?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. They say here 85% of</p> <p>14 oxycodone 30 milligrams sent to Florida is</p> <p>15 diverted, right?</p> <p>16 A. That's what DEA told us, yes.</p> <p>17 Q. So what's happening is customers,</p> <p>18 distributors, wholesalers buying the drug in</p> <p>19 Florida or customers of their customers bringing</p> <p>20 the drug into Florida, that drug is then leaving</p> <p>21 Florida and going elsewhere in the country,</p> <p>22 right?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 THE WITNESS: I don't know if</p>

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<p style="text-align: right;">Page 222</p> <p>1 they were saying it was leaving Florida.  2 They were just saying that it was being  3 diverted. It wasn't getting to a  4 legitimate channel somewhere down the  5 line.  6 BY MR. BUCHANAN:  7 Q. Fair enough, okay. Got it. So  8 if -- whether it stayed in Florida or whether it  9 left Florida, it wasn't landing in the channel  10 where it was supposed to land, right?  11 A. Correct.  12 Q. Fair enough, okay. Then it said,  13 the "US uses 90-95% of the hydrocodone produced"  14 worldwide. It doesn't say worldwide, but you  15 understood that from your meeting, right?  16 MS. VANNI: Object to form.  17 THE WITNESS: Yes.  18 BY MR. BUCHANAN:  19 Q. Okay. So of all of the people in  20 the world with all of their maladies and all of  21 their pain and all of their conditions, this  22 country uses 90 to 95% of all the hydrocodone  23 produced in the world, right?  24 MS. VANNI: Object to form.</p>	<p style="text-align: right;">Page 224</p> <p>1 people in other countries, right?  2 MS. VANNI: Object to form.  3 THE WITNESS: I don't know if you  4 could make that assumption.  5 BY MR. BUCHANAN:  6 Q. You're not aware of that?  7 A. No, I'm not.  8 Q. You're not aware that --  9 A. I don't have any knowledge of  10 what goes on in other countries.  11 Q. But as a person engaged in DEA  12 compliance, I mean, do you look to see, I mean,  13 what the trends are with regard to the use of  14 the products that your manufacturers or  15 distributors are making or distributing?  16 A. I look at some data, but a lot of  17 data is not -- not represented well, I don't  18 think, and it doesn't have the level of detail  19 that it needs to accurately focus or address the  20 problem.  21 Q. Well then, certainly, you'd want  22 to be really cautious, right?  23 MS. VANNI: Object to form.  24 THE WITNESS: Yes.</p>
<p style="text-align: right;">Page 223</p> <p>1 THE WITNESS: That was my  2 understanding from what they were  3 saying, yes.  4 BY MR. BUCHANAN:  5 Q. Would it be fair to say, ma'am,  6 that we don't have 90 to 95% of the world's  7 population?  8 MS. VANNI: Object to form.  9 THE WITNESS: I'm not sure. I  10 guess you could say that. I don't know.  11 I don't know what the population is in  12 every country.  13 BY MR. BUCHANAN:  14 Q. Well, worldwide, internationally,  15 there are organizations that monitor the use of  16 opioids country by country, right?  17 A. Mm-hmm. What it tells me is that  18 we're more humane in the United States and we  19 treat pain as compared to some third world  20 countries, for example.  21 Q. There's another part of that,  22 right?  23 A. Mm-hmm.  24 Q. We abuse opioids more than other</p>	<p style="text-align: right;">Page 225</p> <p>1 BY MR. BUCHANAN:  2 Q. And you'd be -- want to be really  3 cautious because if we're talking about products  4 that have to be kept in cages or have to be kept  5 in vaults or have to be handled by two people at  6 the same time because we can't really trust one  7 person or the other not to take this and divert  8 it, we've got to be really cautious in how we  9 distribute or sell these types of drugs, fair?  10 MS. VANNI: Objection.  11 THE WITNESS: Yes, and we were.  12 BY MR. BUCHANAN:  13 Q. And I move to strike the end. If  14 you could stay with my question, ma'am.  15 It says, "you need to visit your  16 customers."  17 That was a takeaway, right?  18 A. Yes.  19 Q. Okay. That was what they told  20 you. The "you" is Qualitest being told by the  21 DEA that you need to visit your customers,  22 right?  23 MS. VANNI: Object to the form.  24 THE WITNESS: Yes.</p>

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<p style="text-align: right;">Page 226</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. And they told you, "we have a</p> <p>3 problem with companies using" who?</p> <p>4 A. "Their sales force to conduct</p> <p>5 visits."</p> <p>6 Q. Right. Because the sales force</p> <p>7 have a conflict or a perceived conflict because</p> <p>8 sales is trying to sell, right?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. So you were told that the DEA had</p> <p>13 a problem with companies using their sales force</p> <p>14 to conduct visits, and they said, as we looked</p> <p>15 on the slide, we "must have a closed system,"</p> <p>16 right?</p> <p>17 A. Yes.</p> <p>18 Q. Told that in 2013, but, frankly,</p> <p>19 as somebody in this space for 25 years, you</p> <p>20 didn't need to hear that from the DEA, right?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: I guess not, but</p> <p>23 it's always good to, you know, make sure</p> <p>24 they haven't changed anything around,</p>	<p style="text-align: right;">Page 228</p> <p>1 THE WITNESS: Not -- not all of</p> <p>2 them, no.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. Well, okay. I mean, if they're</p> <p>5 engaging in this, if they're pharmacies, for</p> <p>6 example, the only way you're going to see it is</p> <p>7 if you go, right?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. They said Georgia,</p> <p>10 Tennessee, Kentucky and Ohio is now a problem,</p> <p>11 right?</p> <p>12 A. Yes.</p> <p>13 Q. Did you have that understanding,</p> <p>14 ma'am, that Ohio was also a problem?</p> <p>15 A. Not until I was told by DEA.</p> <p>16 Q. So as some -- we could agree that</p> <p>17 during your entire time at Qualitest, the</p> <p>18 company was selling drugs into the Ohio</p> <p>19 community, true?</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: The company sold</p> <p>22 drugs into a lot of states.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Every state, as far as you know,</p>
<p style="text-align: right;">Page 227</p> <p>1 yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Right. I mean, that's part of</p> <p>4 the registration process we talked about that</p> <p>5 every registrant in this system has got to do</p> <p>6 their job, right?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. "At customer locations,</p> <p>9 look for," and what do they tell you to look</p> <p>10 for?</p> <p>11 A. Location of pharmacy, lines going</p> <p>12 out the door, cars with out-of-state license</p> <p>13 plates, doctors who prescribe the same NDC,</p> <p>14 patients who get the same script, "everybody has</p> <p>15 lower back pain."</p> <p>16 Q. Okay. And why look for those</p> <p>17 things?</p> <p>18 A. They're indicators of</p> <p>19 potential -- potential pill mills or diversion.</p> <p>20 Q. Right. And these are things that</p> <p>21 you see when you actually go -- you can see, are</p> <p>22 capable of seeing when you actually put boots on</p> <p>23 the ground and go to see customers, right?</p> <p>24 MS. VANNI: Object to form.</p>	<p style="text-align: right;">Page 229</p> <p>1 right?</p> <p>2 A. As far as I know, yes.</p> <p>3 Q. Okay. So, certainly, selling the</p> <p>4 drug directly into Ohio or to Ohio distributors</p> <p>5 or wholesalers, right?</p> <p>6 A. Yes.</p> <p>7 Q. And certainly wouldn't be</p> <p>8 surprised if the drug that Qualitest was making</p> <p>9 was landing in Ohio pharmacies, right?</p> <p>10 MS. VANNI: Object to form.</p> <p>11 THE WITNESS: Potentially, yes.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. And could you tell the jury,</p> <p>14 please, when was the first time that Qualitest</p> <p>15 conducted a due diligence visit on an Ohio</p> <p>16 pharmacy?</p> <p>17 A. I cannot tell you right now. I'm</p> <p>18 not sure off the top of my head.</p> <p>19 Q. Are you aware of any prior to</p> <p>20 2013, ma'am?</p> <p>21 A. We would have had due diligence</p> <p>22 visits conducted. It would have been by the</p> <p>23 sales team. I'm not sure if they were in Ohio</p> <p>24 or not.</p>

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<p style="text-align: right;">Page 230</p> <p>1 Q. Are you aware of any visits into 2 Ohio by the sales team or otherwise prior to 3 2013? 4 A. I would not know, since I wasn't 5 there. 6 Q. And, frankly, if it happened 7 prior to 2013, you're saying I'd have to go talk 8 to a sales rep? 9 A. Not a sales rep. 10 MS. VANNI: Object to form. 11 THE WITNESS: One of the more -- 12 the sales team that would be internal, 13 not necessarily a sales rep outside. 14 BY MR. BUCHANAN: 15 Q. Well, certainly, the company and 16 its compliance -- this was a compliance function 17 you're saying was happening? 18 A. The visits? 19 Q. Mm-hmm. 20 A. It was a compliance function 21 later, after we -- after we had the personnel 22 and we started doing them. 23 Q. Okay. Well, I just want to 24 understand the -- kind of the visits you're</p>	<p style="text-align: right;">Page 232</p> <p>1 Q. Right. 2 So let's -- I just want to 3 understand whether these visits by salespeople 4 that may or may not have happened, I mean, was 5 that being done as a formal compliance effort, 6 where you were generating due diligence files? 7 MS. VANNI: Object to form. 8 THE WITNESS: I can't say if they 9 were or not. 10 BY MR. BUCHANAN: 11 Q. Are you aware of any that 12 happened prior to 2013? 13 A. I don't know either way. 14 Q. Okay. All right. So what the 15 DEA is telling you or at least your takeaway 16 from this meeting in March is, one, you've got 17 to get to know your customers, right? 18 A. Yes. 19 Q. And they also told you you got to 20 get to know your customers' customers, right? 21 A. To the extent you can, yes. 22 Q. They told you Ohio is a problem, 23 Florida is a problem, right? 24 MS. VANNI: Object to form.</p>
<p style="text-align: right;">Page 231</p> <p>1 saying may have served the same function at 2 earlier points in time that you're not sure 3 actually happened in Ohio. 4 Was that being done as, you know, 5 as a know your customer anti-diversion effort; 6 is that what you're saying? 7 MS. VANNI: Object to the form. 8 THE WITNESS: I really don't 9 know. I can't comment since I wasn't 10 there. 11 BY MR. BUCHANAN: 12 Q. Well, surely if this was being 13 done as part of a compliance function, you'd 14 maintain records of due diligence visits like 15 that, right? 16 MS. VANNI: Object to form. 17 THE WITNESS: Not necessarily. 18 DEA didn't -- they didn't really talk 19 about documenting your due diligence 20 until more recent -- you know, not more 21 recent like this year but, you know, 22 till later on. As I said, the program, 23 the SOM program changed over time so... 24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 233</p> <p>1 THE WITNESS: Yes. 2 BY MR. BUCHANAN: 3 Q. You had that knowledge, though, 4 that Florida today was an issue even before the 5 DEA told you, right? 6 A. Mainly because of seeing it on 7 presentations that they had given, yes. 8 Q. Right. I mean, you knew that 9 licenses were getting suspended of 10 distributorships and pharmacies were getting 11 shuttered in -- I shouldn't say shuttered -- the 12 DEA was taking their license, right? 13 MS. VANNI: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BUCHANAN: 16 Q. I guess they could continue to 17 sell noncontrolled substances and chewing gum 18 and milk and stuff, but they couldn't sell 19 controlled substances after that point, right? 20 A. Yes. 21 Q. And hefty fines were levied, 22 right? 23 MS. VANNI: Object to form. 24 THE WITNESS: Yes.</p>



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<p style="text-align: right;">Page 234</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Okay. They then tell you that</p> <p>3 "keep a filing system on customers reported to</p> <p>4 DEA and a database on due diligence."</p> <p>5 Do you see that?</p> <p>6 A. That's --</p> <p>7 Q. Database on due diligence?</p> <p>8 A. Yes, that's exactly where they</p> <p>9 started talking about writing, documenting your</p> <p>10 due diligence.</p> <p>11 Q. And we'll look at some of your</p> <p>12 earlier documents that precede this meeting. I</p> <p>13 mean, you knew about the DEA's know your</p> <p>14 customer initiative well before March of 2013,</p> <p>15 didn't you, ma'am?</p> <p>16 MS. VANNI: Object to form.</p> <p>17 THE WITNESS: Prior to this</p> <p>18 meeting, I'm sure it was mentioned at</p> <p>19 conferences, know your customer.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Right. And this, as you said, as</p> <p>22 expected, and the other e-mail and then you</p> <p>23 described what happened at the meeting.</p> <p>24 Do you recall that?</p>	<p style="text-align: right;">Page 236</p> <p>1 believe they were referring to pharmacies at</p> <p>2 that point.</p> <p>3 Q. Okay. And so one of the things</p> <p>4 you could do is you could look through IMS data</p> <p>5 or you could look through prescription level</p> <p>6 data if you got it through questionnaires or</p> <p>7 through dispensing histories from pharmacies or</p> <p>8 you could get it from your distributor customers</p> <p>9 if they provided it to you, you could see the</p> <p>10 relative balance of controlled substances versus</p> <p>11 noncontrolled substances, right?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: Absolutely not. So</p> <p>14 as a manufacturer, we were not entitled</p> <p>15 to dispensing data, for one. We would</p> <p>16 not be getting dispensing data. It</p> <p>17 would be a HIPAA violation if it wasn't</p> <p>18 cleansed from patient information for</p> <p>19 one.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Okay. Maybe my question was</p> <p>22 confusing then.</p> <p>23 And we'll look at this, provided</p> <p>24 I still have time, the company after it</p>
<p style="text-align: right;">Page 235</p> <p>1 A. I do.</p> <p>2 Q. Yes. So what's happening here,</p> <p>3 and I guess you got some visibility in the</p> <p>4 charts as to your customers' customers and what</p> <p>5 their transactions were?</p> <p>6 A. Yes.</p> <p>7 Q. But you were aware that the DEA</p> <p>8 had a know your customer expectation before this</p> <p>9 meeting, right?</p> <p>10 MS. VANNI: Object to form.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. Okay. And they said average</p> <p>14 customer purchases, 15% controlled substances --</p> <p>15 excuse me.</p> <p>16 "Average customer purchases 15%</p> <p>17 controlled substances and 85% noncontrolled; IMS</p> <p>18 shows an average of 13.8% controlled</p> <p>19 substances."</p> <p>20 So what's going on there?</p> <p>21 A. Those were numbers that were</p> <p>22 provided by DEA as guidance as to the split that</p> <p>23 customers should have between controlled and</p> <p>24 noncontrolled, and it doesn't say it here, but I</p>	<p style="text-align: right;">Page 237</p> <p>1 implemented its revised SOMS actually requested</p> <p>2 from its customers and from some of its</p> <p>3 customers' customers dispensing data that showed</p> <p>4 aggregate purchases of controlled substances</p> <p>5 versus noncontrolled substances, correct?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: I don't know</p> <p>8 after -- I'm not sure. I don't believe</p> <p>9 so.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. While you were there it happened.</p> <p>12 Do you recall that?</p> <p>13 A. I recall looking at IMS data for</p> <p>14 the national averages. I don't recall actually</p> <p>15 getting dispensing data.</p> <p>16 Q. Okay. We'll see if we can fill</p> <p>17 in that -- your memory on that if we have time.</p> <p>18 A. Okay.</p> <p>19 Q. But one of the things you can do,</p> <p>20 obviously, is you can see is this pharmacy</p> <p>21 behaving like a pharmacy. Is it purchasing</p> <p>22 roughly 13 to 15% controlled substances, or is</p> <p>23 it doing something different? Is it buying 30,</p> <p>24 40, 50%, right?</p>

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<p style="text-align: right;">Page 238</p> <p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: Yes, and it's a</p> <p>3 guidance.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. Right, because it could be that</p> <p>6 there's a unique circumstance for that</p> <p>7 particular pharmacy. It might be a small one.</p> <p>8 It might have a particular reason why it's 16%</p> <p>9 rather than 13%, whatever the numbers are?</p> <p>10 A. Correct.</p> <p>11 Q. So you've got to think, right?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. So you get red flags -- well,</p> <p>16 let's take a step back.</p> <p>17 The process, as I understand it</p> <p>18 is, one, we should get information, right;</p> <p>19 that's what you're being told?</p> <p>20 A. Yes.</p> <p>21 Q. As a participant in this closed</p> <p>22 system, you have an obligation to get</p> <p>23 information on your customers, correct?</p> <p>24 MS. VANNI: Object to form.</p>	<p style="text-align: right;">Page 240</p> <p>1 not rare that you have choice?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: No, I'm saying it's</p> <p>4 rare that a customer would not cooperate</p> <p>5 but...</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. Right, right. So we will see</p> <p>8 some examples. You recall some customers who</p> <p>9 didn't cooperate?</p> <p>10 A. Yes.</p> <p>11 Q. Some distributors who didn't</p> <p>12 cooperate, right?</p> <p>13 MS. VANNI: Objection.</p> <p>14 THE WITNESS: I don't believe so,</p> <p>15 but...</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Some distributors who didn't give</p> <p>18 you their SOM information or had no SOM program.</p> <p>19 Do you recall that?</p> <p>20 MS. VANNI: Objection.</p> <p>21 THE WITNESS: I do not.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. Because that would be a concern,</p> <p>24 right, if it --</p>
<p style="text-align: right;">Page 239</p> <p>1 THE WITNESS: Correct.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. And you have an obligation to get</p> <p>4 information on your customers' customers, right?</p> <p>5 MS. VANNI: Object to form.</p> <p>6 THE WITNESS: To the extent you</p> <p>7 can, yes.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. Right. And so, look, you could</p> <p>10 have difficult customers who don't cooperate,</p> <p>11 that's one thing, correct?</p> <p>12 A. Mm-hmm, yes.</p> <p>13 Q. And you can choose not to do</p> <p>14 business with them?</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Every manufacturer, every</p> <p>19 distributor has that choice, correct?</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: That's rare.</p> <p>22 That's rare, but...</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Well, you have a choice. That's</p>	<p style="text-align: right;">Page 241</p> <p>1 A. Yes.</p> <p>2 Q. Somebody you were selling drug to</p> <p>3 didn't have a SOM program, right?</p> <p>4 MS. VANNI: Objection.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. When I say "SOM," I mean a</p> <p>7 distributor.</p> <p>8 A. It would depend on controls they</p> <p>9 have in place, other controls that -- maybe</p> <p>10 they're not calling it a SOMS program, but they</p> <p>11 have some things in place. It depends on the</p> <p>12 situation.</p> <p>13 Q. Okay. So let's take the -- let's</p> <p>14 take the name off of it, whether they call it a</p> <p>15 SOM program. It would be of concern to you,</p> <p>16 ma'am, if somebody in this field, if a customer</p> <p>17 of a manufacturer, a distributor or a wholesaler</p> <p>18 didn't have a program, whether by name or</p> <p>19 function, to serve SOM purposes, correct?</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: Yes.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. In fact, I mean, you identified</p> <p>24 that as a concern at various points in time</p>

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<p style="text-align: right;">Page 242</p> <p>1 after you implemented SOPs at Qualitest, 2 correct? 3 A. Yes. 4 Q. That if somebody doesn't give you 5 SOM information, we should not be selling to 6 them, right? 7 MS. VANNI: Object to form. 8 THE WITNESS: Again, depending on 9 the scenario, the situation. 10 BY MR. BUCHANAN: 11 Q. Do you recall giving that 12 guidance? 13 A. Yes. 14 Q. Because if your customers don't 15 have SOM programs in place, there can be no 16 assurance that you're living up to your promise 17 to get your registration that you're going to 18 maintain effective controls against diversion, 19 right? 20 MS. VANNI: Object to form. 21 THE WITNESS: Again, it depends 22 on the controls that the customer has in 23 place and the situation. 24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 244</p> <p>1 getting back to it, I'm sorry, 657.1, we're 2 going to go to "If we decide to terminate a 3 customer, we should let both the local and HQ 4 offices of DEA know." 5 Do you see that? 6 A. Yes. 7 Q. Do you agree with that, that's 8 something you should do? 9 A. It depends on, again, on the 10 situation. If we're terminating a customer for 11 a -- for a reason that isn't causing any 12 diversion or abuse or we don't have a suspicion 13 about that customer, then no there's no reason 14 to let DEA know. 15 Q. Right. I mean, if you're 16 terminating a customer because you believe 17 they're either a suspicious customer or they've 18 -- their orders are suspicious, you got to let 19 the DEA know, right, no question? 20 MS. VANNI: Object to form. 21 THE WITNESS: The regulation is 22 you notify them of suspicious orders. 23 It's not -- the regulation doesn't 24 require you to notify them if you just</p>
<p style="text-align: right;">Page 243</p> <p>1 Q. Well, the controlled system 2 doesn't work if you sell it to people who are 3 putting their head in the sand; we can agree on 4 that? 5 A. Yes. 6 MS. VANNI: Object to form. 7 BY MR. BUCHANAN: 8 Q. And the system doesn't work if 9 you're selling to people who don't have by name 10 or function suspicious order monitoring 11 programs, correct? 12 MS. VANNI: Object to form. 13 THE WITNESS: Yes. 14 BY MR. BUCHANAN: 15 Q. Okay. And suspicious order 16 monitoring programs have been either statutorily 17 or regulatory required for as long as you've 18 been in dealing with controlled substances, 19 correct? 20 A. Yes. 21 Q. And that takes us back to the 22 late '80s? 23 A. Yes. 24 Q. Okay. So next bullet was --</p>	<p style="text-align: right;">Page 245</p> <p>1 terminate them as a customer. 2 BY MR. BUCHANAN: 3 Q. Okay. So these were your high 4 level takeaways from the meeting the next day? 5 A. Yes. 6 Q. And then I know you implemented a 7 process, and we'll talk about that in a moment, 8 about what you started to do to kind of bring 9 Qualitest SOMS procedures in line, fair? 10 MS. VANNI: Objection to form. 11 THE WITNESS: No, not fair. It 12 was -- 13 BY MR. BUCHANAN: 14 Q. Okay. We'll see whether it's 15 fair in a moment, so let's pause. 16 (Document marked for 17 identification as Par-Norton Deposition 18 Exhibit No. 10.) 19 MR. BUCHANAN: I'm going to pass 20 you what we're marking -- it's 1044, 21 Scott -- next in order is Exhibit 10, 22 ma'am. 23 BY MR. BUCHANAN: 24 Q. Aimee Cooper was someone who</p>

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<p style="text-align: right;">Page 246</p> <p>1 worked in your organization in compliance?  2 MS. VANNI: Can I have a copy?  3 THE WITNESS: Yes.  4 MR. BUCHANAN: Oh, sorry. It  5 should have gone to you first.  6 MS. VANNI: Thank you.  7 BY MR. BUCHANAN:  8 Q. All right. So Aimee Cooper was  9 with you. I guess this is from 2017, but she's  10 forwarding along in the minutes from the  11 March 27 meeting?  12 A. Mm-hmm.  13 Q. I'm sorry, not the March 27  14 meeting. The minutes are stamped March 27,  15 2013.  16 You see the memorandum on the  17 next page?  18 A. Yes.  19 Q. And so what's happening here is I  20 guess at a later point in time in 2017, there's  21 a need to look back at the -- what happened in  22 March of 2013, and they're being forwarded  23 along.  24 Do you recognize the format of</p>	<p style="text-align: right;">Page 248</p> <p>1 Ms. Boockholdt was at the  2 meeting?  3 A. I believe so, yes.  4 Q. Do you know how to pronounce her  5 name?  6 A. Boockholdt.  7 Q. Boockholdt, thank you.  8 And she's with the Office of  9 Diversion Control, and she's writing to I guess  10 one of her colleagues?  11 A. Rannazzisi was in charge of DEA.  12 Q. And who is he -- oh, in charge of  13 DEA?  14 A. Yes.  15 Q. Okay. And he had been talking  16 and writing and speaking about diversion,  17 anti-diversion, suspicious order monitoring for  18 some time, fair?  19 MS. VANNI: Object to form.  20 THE WITNESS: I would assume,  21 yes.  22 BY MR. BUCHANAN:  23 Q. Well, you've been in this space  24 for a while, right?</p>
<p style="text-align: right;">Page 247</p> <p>1 the memo that's reflected on page 2?  2 MS. VANNI: Object to the  3 colloquy.  4 THE WITNESS: I recognize the  5 format. I'm not sure if I had a copy  6 before I left. This appears to be an  7 internal DEA document.  8 BY MR. BUCHANAN:  9 Q. Okay.  10 A. So it may have been obtained  11 through Freedom of Information, I'm not sure.  12 Q. So manufacturers can request  13 information from the DEA through informal  14 process and also formal process, right?  15 A. Through formal process and at  16 this point it takes years to get it, so, yeah.  17 Q. Okay. So we have here the  18 minutes from the DEA of the meeting, and let's  19 pull those up.  20 It's from a Barbara Boockholdt,  21 chief regulatory section ODG, Office of  22 Diversion Control to a Joseph Rannazzisi, deputy  23 assistant administrator, Office of Diversion  24 Control.</p>	<p style="text-align: right;">Page 249</p> <p>1 A. Yes.  2 Q. Okay. "Space" meaning suspicious  3 order monitoring, DEA compliance, right?  4 A. Correct.  5 Q. You remember in the mid-2000s  6 receiving letters from Mr. Rannazzisi, right?  7 MS. VANNI: Object to form.  8 THE WITNESS: I remember  9 receiving letters. I don't recall if  10 they came from Mr. Rannazzisi, but, yes,  11 we did receive letters.  12 BY MR. BUCHANAN:  13 Q. Okay. Letters concerning either  14 manufacturers' obligations or distributor  15 obligations with regard to maintaining effective  16 controls against diversion?  17 A. Yes.  18 Q. Okay. And so that's all  19 information that you as somebody in regulatory  20 compliance take into consideration in designing  21 programs to maintain effective controls against  22 diversion, true?  23 MS. VANNI: Object to form.  24 THE WITNESS: Yes.</p>

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<p style="text-align: right;">Page 250</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Okay. So let's look at this one.</p> <p>3 This is a recap of the meeting from the</p> <p>4 perspective of the DEA. Can we scroll down.</p> <p>5 Probably the second paragraph is where we get</p> <p>6 into the meat of it.</p> <p>7 Do you see that?</p> <p>8 A. Okay.</p> <p>9 Q. Okay?</p> <p>10 A. "SC Levin opened."</p> <p>11 Q. SC Levin, do you know SC Levin?</p> <p>12 A. Yes.</p> <p>13 Q. What's that C stand for?</p> <p>14 A. Special -- staff coordinator.</p> <p>15 Q. Got you. Staff coordinator</p> <p>16 Levin, somebody with the DEA?</p> <p>17 A. Yes, headquarters.</p> <p>18 Q. And just to orient us, where --</p> <p>19 this is a summary of, I guess, Barbara</p> <p>20 Boockholdt of what happened at the meeting three</p> <p>21 weeks earlier with you?</p> <p>22 A. I believe so, yes.</p> <p>23 Q. Okay. SC Levin opened the</p> <p>24 meeting by stating the purpose was both</p>	<p style="text-align: right;">Page 252</p> <p>1 suspicious order monitoring system."</p> <p>2 Do you see that, ma'am?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And it talks about</p> <p>5 Qualitest and its locations and then there's a</p> <p>6 sentence attributed to you.</p> <p>7 Ms. Hernandez was aware of the</p> <p>8 chargeback system utilized by manufacturers,</p> <p>9 including Qualitest, but stating that the firm</p> <p>10 has not reviewed it.</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Do you recall discussing that</p> <p>14 with the DEA?</p> <p>15 A. Yes, I do.</p> <p>16 Q. Okay. And that accurately sets</p> <p>17 forth at least that portion of the discussion,</p> <p>18 right?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. "Ms. Hernandez stated the</p> <p>21 firm's suspicious order monitoring system is a</p> <p>22 work in progress."</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 251</p> <p>1 educational and informative. SC Levin stated he</p> <p>2 would discuss Qualitest's responsibilities under</p> <p>3 the Controlled Substances Act, their suspicious</p> <p>4 order monitoring system, their procedures</p> <p>5 concerning due diligence, knowing their</p> <p>6 customers, who their customers sell to and</p> <p>7 graphs depicting the pharmacies and</p> <p>8 practitioners where oxycodone in various</p> <p>9 formulations and hydrocodone in various</p> <p>10 formulations were ultimately dispensed from.</p> <p>11 Do you see that, ma'am?</p> <p>12 A. Yes.</p> <p>13 Q. And as an encapsulation, is that</p> <p>14 a good high level summary of what happened</p> <p>15 during the meeting?</p> <p>16 MS. VANNI: Object to form.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Okay. It states that in the next</p> <p>20 paragraph, after summarizing Qualitest, I think</p> <p>21 it's the third sentence or fourth sentence, it</p> <p>22 says Ms. Hernandez -- well, let's read it. "SC</p> <p>23 Levin asked Ms. Hernandez to talk briefly about</p> <p>24 Qualitest, their product line and their</p>	<p style="text-align: right;">Page 253</p> <p>1 Q. "And it is currently based on</p> <p>2 historical purchases by an individual customer</p> <p>3 (thresholds)."</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes, you did.</p> <p>6 Q. Okay. Stated that you do not</p> <p>7 routinely visit customers to determine who they</p> <p>8 are selling to and "Qualitest does not visit</p> <p>9 their pharmacies or practitioners who dispense</p> <p>10 their product."</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Do you recall discussing that</p> <p>14 with the DEA?</p> <p>15 A. I do.</p> <p>16 Q. So you don't dispute the</p> <p>17 characterization of the meeting?</p> <p>18 A. No.</p> <p>19 Q. Okay. "Ms. Hernandez stated the</p> <p>20 only individuals who visit their customers are</p> <p>21 from the sales force and not compliance."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. It notes that you're currently</p>

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<p style="text-align: right;">Page 254</p> <p>1 seeking to update your computer system and to</p> <p>2 improve the suspicious order monitoring system.</p> <p>3 Do you see that?</p> <p>4 A. Yes, I do.</p> <p>5 Q. Okay. Apparently, you presented</p> <p>6 some organizational structure of Endo and the</p> <p>7 subsidiaries, and then you "stated that over 50</p> <p>8 percent of the firm's sales are controlled</p> <p>9 substances."</p> <p>10 Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. I want to focus on the next</p> <p>13 paragraph.</p> <p>14 "SC Levin stated that 80 percent</p> <p>15 of all controlled substances manufactured in the</p> <p>16 world are prescribed and consumed in the United</p> <p>17 States."</p> <p>18 Do you recall this discussion?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. SC Levin stated that the</p> <p>21 abuse and diversion of oxycodone 15 and</p> <p>22 30-milligram tablets is a major problem.</p> <p>23 Do you recall that?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 256</p> <p>1 reflected in your takeaway bullet points, fair?</p> <p>2 A. Yes.</p> <p>3 Q. Okay.</p> <p>4 A. He's basically going over the</p> <p>5 regulations in general and the things that</p> <p>6 they're seeing.</p> <p>7 Q. Okay. Also says, you know, you</p> <p>8 should be reviewing what the DEA has done, our</p> <p>9 investigations, things that you read more</p> <p>10 publicly on websites concerning customers and</p> <p>11 customers of customers, fair?</p> <p>12 A. Yes.</p> <p>13 Q. And then it talks about the</p> <p>14 PowerPoint that he presented and some bullets</p> <p>15 that we don't need to revisit in great depth</p> <p>16 but, again, echoing this concept that closed</p> <p>17 system of controlled substance distribution,</p> <p>18 correct?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. And then it notes what the graphs</p> <p>23 depicted at the end of the first page, yes. The</p> <p>24 graphs depicted or the graphs revealed several</p>
<p style="text-align: right;">Page 255</p> <p>1 Q. Do you recall that being a major</p> <p>2 problem at this point in time?</p> <p>3 MS. VANNI: Object to form.</p> <p>4 THE WITNESS: I recall him saying</p> <p>5 it was a major problem, yes.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. Okay. "SC Levin discussed the</p> <p>8 pain clinic issues found in Florida, as well as</p> <p>9 other drug abuse trends across the country. SC</p> <p>10 Levin outlined the methods of diversion of these</p> <p>11 products and advised that Qualitest is</p> <p>12 responsible for monitoring and reviewing their</p> <p>13 suspicious order monitoring system, assuring</p> <p>14 Qualitest is reporting to ARCOS correctly,</p> <p>15 visiting and knowing their customers,</p> <p>16 maintaining a due diligence file on their</p> <p>17 customers, and knowing where their products are</p> <p>18 ending up."</p> <p>19 Let's pause for a moment. First,</p> <p>20 did I read that correctly?</p> <p>21 A. Yes.</p> <p>22 Q. And you recall that discussion?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And then some of that's</p>	<p style="text-align: right;">Page 257</p> <p>1 pharmacies purchasing large quantities of</p> <p>2 oxycodone and hydrocodone products from</p> <p>3 Qualitest's customers. The graph showed the</p> <p>4 pharmacies in Florida purchased very large</p> <p>5 quantities of Qualitest's oxycodone products.</p> <p>6 Also, the graphs show that pharmacies in Texas</p> <p>7 and California purchased large quantities of</p> <p>8 Qualitest's hydrocodone products.</p> <p>9 Ms. Hernandez, Ms. Hudson and Ms. Patel were</p> <p>10 completely unaware of where Qualitest products</p> <p>11 were ending up.</p> <p>12 As of that point in time, ma'am,</p> <p>13 were you completely unaware of where Qualitest's</p> <p>14 products were ending up?</p> <p>15 A. No. What this refers to is that</p> <p>16 we were unaware of the secondary customers. So</p> <p>17 we ship to the customers and we were aware who</p> <p>18 we were shipping to and, you know, the</p> <p>19 information for them, but we did not have</p> <p>20 visibility of the customers that they then</p> <p>21 shipped to.</p> <p>22 Q. Right, as of that point in time,</p> <p>23 ma'am, you were not looking at really the</p> <p>24 customers of customers in terms of what they</p>

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<p style="text-align: right;">Page 258</p> <p>1 were receiving, right?</p> <p>2 A. Correct. We didn't have data</p> <p>3 available to us.</p> <p>4 Q. Well, there is chargeback data</p> <p>5 that the company ultimately looked at, fair?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: Yes, that gave</p> <p>8 us --</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. In fact, the DEA told you you</p> <p>11 need to be looking at that, right?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: The DEA told us</p> <p>14 that we should look at it because that's</p> <p>15 what they were hearing from other</p> <p>16 manufacturers, that they were looking</p> <p>17 into that and trying to see if they</p> <p>18 could get data from it.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. And, in fact, you contracted to</p> <p>21 after this meeting and started to implement a</p> <p>22 process where you reviewed and considered</p> <p>23 chargeback data, correct?</p> <p>24 A. Yes, we did try.</p>	<p style="text-align: right;">Page 260</p> <p>1 and as seen in their ARCOS data," is what, what</p> <p>2 did he say?</p> <p>3 A. He said "inadequate to say the</p> <p>4 least."</p> <p>5 Q. Do you recall this discussion</p> <p>6 with the DEA in March of 2013?</p> <p>7 A. I don't recall it being said to</p> <p>8 us as being inadequate during the meeting.</p> <p>9 I do recall us telling them of</p> <p>10 some of the things that we were looking at and</p> <p>11 wanted to implement and them stating that that</p> <p>12 was good, that they, you know, supported that</p> <p>13 and that we should move forward with taking</p> <p>14 those additional steps.</p> <p>15 Q. And they gave you a window of</p> <p>16 time to do this, and they were going to come</p> <p>17 back and talk to you to make sure you had done</p> <p>18 it, right?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: I don't believe --</p> <p>21 I don't believe there was a you must</p> <p>22 follow up with us type of mentality. I</p> <p>23 think that was us saying we wanted to go</p> <p>24 back and talk to DEA and show them the</p>
<p style="text-align: right;">Page 259</p> <p>1 Q. Okay. You, in fact, did</p> <p>2 implement the consideration of chargeback data</p> <p>3 as part of your SOMS process, correct?</p> <p>4 A. Not while I was at Qualitest. It</p> <p>5 was something -- I don't know if anything was --</p> <p>6 happened afterwards, but while I was there, we</p> <p>7 were not able to get any good data out of it.</p> <p>8 Q. Okay. Let's pause and see if I</p> <p>9 can refresh your memory on that during our</p> <p>10 examination today.</p> <p>11 A. Sure.</p> <p>12 Q. It then continues that "SC Levin</p> <p>13 stated that Qualitest must review the chargeback</p> <p>14 information which they have access to,</p> <p>15 immediately address deficiencies in their</p> <p>16 suspicious order monitoring system, have</p> <p>17 compliance people visit their customers to</p> <p>18 review their suspicious order monitoring system</p> <p>19 and review the top customers of their customers</p> <p>20 and pay visits to pharmacies that purchase their</p> <p>21 products. SC Levin advised Ms. Hernandez that</p> <p>22 Qualitest must know their customers and maintain</p> <p>23 a due diligence file on them. SC Levin stated</p> <p>24 Qualitest's current system as explained to him</p>	<p style="text-align: right;">Page 261</p> <p>1 things we had implemented.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. It stated that "SC Levin stated</p> <p>4 that should Qualitest or any firm who had been</p> <p>5 briefed was found to have violated the CSA</p> <p>6 pertaining to what was discussed during the</p> <p>7 course of the meeting, DEA could seek</p> <p>8 administrative or civil action to remedy the</p> <p>9 violation."</p> <p>10 Did I read that correctly?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. You were further guided, I</p> <p>13 think it's the last sentence here. SC Levin</p> <p>14 told Ms. Hernandez to educate Qualitest</p> <p>15 employees who have access to controlled</p> <p>16 substances on what they discussed today -- or</p> <p>17 what was discussed today and communicate with</p> <p>18 her local DEA office, should she have any</p> <p>19 questions.</p> <p>20 Did I read that correctly?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Well, let's talk -- let's</p> <p>23 talk about the implementation steps. Oh,</p> <p>24 actually, one more document to complete this.</p>

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<p>1 MR. BUCHANAN: 619, please.  2 (Document marked for  3 identification as Par-Norton Deposition  4 Exhibit No. 11.)  5 BY MR. BUCHANAN:  6 Q. I guess before we move off the  7 last exhibit, that generally reflects the  8 meeting and refreshes your recollection what  9 occurred that day?  10 MS. VANNI: Object to form.  11 THE WITNESS: Generally, yes.  12 I'm sure that every distributor had  13 almost word for word the same minutes.  14 BY MR. BUCHANAN:  15 Q. In other words, this was a  16 meeting that was a meeting that was being had  17 generally; is that what you're saying?  18 A. Correct. I mean, it was -- DEA  19 was doing the same meeting with all distributors  20 and basically providing the same message.  21 Q. And so you had that same type of  22 meeting with that same type of message with Anda  23 or Anda back in 2009 or whenever that meeting  24 occurred?</p>	<p>1 A. So I reported to Sanjay, who  2 reported to Jill who reported to Denise.  3 Q. Thank you.  4 A. Sorry.  5 Q. So Ms. Hudson was not able to  6 attend the meeting in person, she participated  7 by phone and took notes while you all were in  8 this discussion with the DEA, fair?  9 A. Yes, with a very bad connection.  10 Q. Okay. All right. Well, let's go  11 midway on point two. What's reflected here in  12 the middle, "Tracey: we were looking at our SOM  13 program just before Lenny called us."  14 You see that in the middle of the  15 page, just kind of a back-and-forth, SOM  16 program?  17 A. Mm-hmm, yes.  18 Q. There's a question about whether  19 you're looking at chargeback data to help you  20 understand what your customers' customers are  21 doing. You respond, "we were looking at our SOM  22 program just before Lenny called us."  23 Do you see that?  24 A. Yes.</p>
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<p>1 MS. KOSKI: Object to form.  2 MR. SCHACK: Objection.  3 THE WITNESS: Yes.  4 MR. BUCHANAN: Thank you.  5 Passing over what we're marking  6 as Exhibit 11. Can we pull up 619 on  7 the screen.  8 BY MR. BUCHANAN:  9 Q. Okay. This is an e-mail from  10 Ms. Hudson to several of the same people we've  11 been talking about, including yourself, Ms.  12 Connell and Sanjay Patel.  13 Do you see that?  14 A. Yes.  15 Q. Denise Hudson worked in your  16 group?  17 A. Denise was -- there was Denise  18 and then Jill and then Sanjay and then myself.  19 Q. Okay. And then the written  20 record won't reflect what you just did, so  21 maybe --  22 A. Sorry.  23 Q. -- you can verbalize that, if you  24 can.</p>	<p>1 Q. Lenny was the local DEA agent?  2 A. Lenny was at headquarters.  3 Q. And Lenny is the one who called  4 you to say we need you to come to DC?  5 A. Yes.  6 Q. Got you, okay.  7 Then you were asked -- you asked  8 to see what your customer SOM program is  9 relative to your products, you responded "Right  10 now, our sales team is visiting our customers."  11 Do you see that?  12 A. Yes.  13 Q. Okay. And then it says, you  14 really need to know who your customers are  15 selling to."  16 Do you see that in the beginning  17 of the next page?  18 A. I do.  19 Q. Okay. And DEA told you, as  20 reflected in Ms. Hudson's notes, "We like to  21 differentiate between salespeople and DEA  22 compliance people."  23 Do you see that?  24 A. Yes.</p>

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<p style="text-align: right;">Page 266</p> <p>1 Q. Do you recall that discussion, at 2 least when you were with the DEA? 3 A. I do. 4 Q. Okay. And then she characterized 5 the discussion this way in the middle of that 6 paragraph, "We want you to look at this, decide 7 what to do about it. If we show up at your 8 facility in 6 to 9 months, we want to see some 9 improvement. We need a good SOM program that is 10 adequate for the type of business we are in. We 11 are responsible for these products. DEA is not 12 interested in interfering with legitimate needs 13 of patients." 14 Do you see that? 15 A. Yes. 16 Q. Did I read that correctly? 17 A. Yes, you did. 18 Q. Okay. And you recall that as 19 being a component of your discussion with the 20 DEA that day? 21 A. I think it's interspersed with 22 some of her opinion as well, but generally, yes. 23 Q. Okay. But you do recall that, in 24 general, that the DEA told you that when we come</p>	<p style="text-align: right;">Page 268</p> <p>1 robust SOM program? 2 MS. VANNI: Object to form. 3 THE WITNESS: Actually, I don't 4 feel -- I don't feel the quantity is a 5 factor. 6 BY MR. BUCHANAN: 7 Q. Okay. A company should have a 8 robust SOM program and strong measures to 9 prevent diversion regardless of the quantity, 10 correct? 11 MS. VANNI: Object to form. 12 THE WITNESS: Yes. 13 BY MR. BUCHANAN: 14 Q. But, certainly, if a company's 15 entire business, to the tune of billions and 16 billions of pills and many billions of dollars 17 in sales is with controlled substances, they 18 should invest the resources in a robust SOM 19 program; you could agree with me, right? 20 MS. VANNI: Object to form. 21 THE WITNESS: Yes. 22 MR. BUCHANAN: So let's -- one 23 other document. Can I have 581. 24 THE VIDEOGRAPHER: Counsel, can</p>
<p style="text-align: right;">Page 267</p> <p>1 back to you in six to nine months, we need 2 improvement? 3 MS. VANNI: Object to form. 4 THE WITNESS: I don't recall. 5 BY MR. BUCHANAN: 6 Q. Okay. It says, "We need a good 7 SOM program that is adequate for the type of 8 business we are in." 9 Do you see that sentence? 10 A. I do. 11 Q. Do you agree, ma'am, as a general 12 matter, that a company needs a SOM program that 13 is adequate for the type of business that it's 14 in? 15 A. Yes. 16 Q. And so if a company is in the 17 business of predominantly making and selling 18 controlled substances, it's got to have a robust 19 SOM program? 20 MS. VANNI: Object to form. 21 THE WITNESS: Yes. 22 BY MR. BUCHANAN: 23 Q. If it's selling 33 billion pills 24 of Vicodin over seven years, it's got to have a</p>	<p style="text-align: right;">Page 269</p> <p>1 we go off the record momentarily. I do 2 apologize, just going off the record 3 momentarily. The time is 1:25 p.m. 4 (Pause.) 5 THE VIDEOGRAPHER: Back on the 6 record, the time is 1:28 p.m. 7 (Document marked for 8 identification as Par-Norton Deposition 9 Exhibit No. 12.) 10 MR. BUCHANAN: Ma'am, passing you 11 what we marked as Exhibit 12. Do we 12 have a copy for counsel yet? It's -- 13 for the record, it's E606 and it's 14 PAR_OPIOID_MDL 18920. 15 MS. VANNI: Thank you. 16 BY MR. BUCHANAN: 17 Q. This is a document from October 18 of 2013, this is some five, six months after 19 your meeting with the DEA, right? 20 A. Yes. 21 Q. Six months to the day almost, 22 right? Mr. Brantley worked in your group? 23 A. He did. 24 Q. Mr. Shaffer worked in your group?</p>

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<p style="text-align: right;">Page 270</p> <p>1 A. Yes.</p> <p>2 Q. So you were the head of DEA</p> <p>3 compliance. You hired Mr. Brantley into your</p> <p>4 group, correct?</p> <p>5 A. Yes, I hired Larry first,</p> <p>6 Mr. Shaffer and then later hired Eric.</p> <p>7 Q. When did you bring in Mr. -- is</p> <p>8 it Shaffer or Shaffer?</p> <p>9 A. Shaffer.</p> <p>10 Q. It's the two Fs that are throwing</p> <p>11 me there.</p> <p>12 A. I'm not sure exactly when.</p> <p>13 Q. I assume his e-mail address is</p> <p>14 spelled right. All right. So when did you hire</p> <p>15 him, by the way?</p> <p>16 A. I'm not sure on exact -- the</p> <p>17 exact date, but he was, I believe, my first</p> <p>18 hire.</p> <p>19 Q. After the meeting with the DEA?</p> <p>20 A. No. After getting to Qualitest.</p> <p>21 Q. Okay. And he was, if I</p> <p>22 understand right, he was more in this quota</p> <p>23 management function, right?</p> <p>24 A. He was at the company, however,</p>	<p style="text-align: right;">Page 272</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Giggled is a confusing term.</p> <p>4 Getting, what, registrations</p> <p>5 pulled, fined, civil actions, suspension orders,</p> <p>6 all that kind of stuff?</p> <p>7 A. Yes, we were tracking it.</p> <p>8 Q. Okay. And so one of the things a</p> <p>9 reasonable company does, and I guess this was a</p> <p>10 responsible thing to do?</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: I think so. I</p> <p>13 think it helped to -- it helped to teach</p> <p>14 others in the company what ramifications</p> <p>15 there were if something were to go</p> <p>16 wrong.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. And that's something that you</p> <p>19 have in a compliance department as a bit of an</p> <p>20 issue from time to time, right?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: No company is</p> <p>23 perfect.</p> <p>24 BY MR. BUCHANAN:</p>
<p style="text-align: right;">Page 271</p> <p>1 he actually had a -- he had handled suspicious</p> <p>2 order monitoring previously.</p> <p>3 Q. Got you.</p> <p>4 All right. So let's look at</p> <p>5 this. This is an e-mail from Mr. Shaffer to</p> <p>6 Mr. Brantley early October 2013, subject SOMS</p> <p>7 info, right?</p> <p>8 A. Yes.</p> <p>9 Q. SOMS violations as a spreadsheet,</p> <p>10 SOMS doc from 2013 and a SOMS presentation,</p> <p>11 right?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. Do you remember during</p> <p>14 your time at the company one of the things you</p> <p>15 were tracking was who was getting in trouble?</p> <p>16 MS. VANNI: Object to form.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. And you had an Excel spreadsheet</p> <p>20 that you put together and kind of tracked what</p> <p>21 was happening with different registrants who was</p> <p>22 getting gigged and written up with big fines and</p> <p>23 stuff like that, right?</p> <p>24 MS. VANNI: Object to form.</p>	<p style="text-align: right;">Page 273</p> <p>1 Q. Certainly not, certainly not, and</p> <p>2 nor are people.</p> <p>3 But one of the issues you have in</p> <p>4 a compliance department is sometimes some</p> <p>5 tension between compliance with what a</p> <p>6 responsible company would do or reasonable</p> <p>7 company would do or the regulations require and</p> <p>8 what the business people want, right?</p> <p>9 MS. VANNI: Objection.</p> <p>10 THE WITNESS: I wouldn't</p> <p>11 necessarily say that there's tension</p> <p>12 from the aspect of, you know, everybody</p> <p>13 knows that you have to comply with the</p> <p>14 DEA regulations. It's a matter of</p> <p>15 education, it really is.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. And so one of the things you did</p> <p>18 was compile a list of all the bad things that</p> <p>19 could happen to us as a business with 70%</p> <p>20 controlled substances if we don't comply, right?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Because this, you know, this is a</p>

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<p style="text-align: right;">Page 274</p> <p>1 -- this could be a devastating consequence if we 2 don't comply, right? 3 MS. VANNI: Object to form. 4 THE WITNESS: Yes. 5 BY MR. BUCHANAN: 6 Q. Fair, yeah. 7 So one of the things that's 8 helpful in certainly getting management's 9 attention is you should know distribution 10 facilities have been closed, right? 11 A. Mm-hmm. 12 Q. That's a yes answer? 13 A. Yes. Sorry. 14 Q. You should know that tens of 15 millions of dollars in fines have been imposed 16 against certain distributors, right? 17 MS. VANNI: Object to form. 18 THE WITNESS: Yes. 19 BY MR. BUCHANAN: 20 Q. You should know that we have a 21 distributor license, right? 22 A. Yes. 23 Q. And if we're not doing our job, 24 this could be devastating, right?</p>	<p style="text-align: right;">Page 276</p> <p>1 saying I needed to make sure I could get some 2 budget to make this happen, so I had to show the 3 other side of not doing it? 4 MS. VANNI: Object to form. 5 THE WITNESS: I was expecting 6 more resistance, yes. 7 BY MR. BUCHANAN: 8 Q. Okay. And so you put together 9 this schedule, and let's look at the -- let's be 10 clear, I guess, because I may not have time to 11 come back to this today. 12 Some of what we see here in the 13 SOMS violations are, for example, we see a 14 reference to Walgreens. 15 MR. BUCHANAN: Could we go to 16 606.4. Can you blow up this one right 17 here, if you can see my finger. Thank 18 you, yeah. My eyes are failing me, 19 guys. Sorry about that. 20 MR. SCHACK: Counsel, do you have 21 any other copies of this exhibit that 22 you can share? 23 MR. BUCHANAN: There's an extra 24 floater if somebody can pass the floater</p>
<p style="text-align: right;">Page 275</p> <p>1 MS. VANNI: Object to form. 2 THE WITNESS: Well, it could 3 impact the business, yes. 4 BY MR. BUCHANAN: 5 Q. Certainly. 6 And so you bring these items to 7 the attention of people above you to say, look, 8 this could affect our pocketbook, right? 9 MS. VANNI: Objection. 10 THE WITNESS: Actually, no. The 11 reason that we use these was because I 12 knew that the electronic system that I 13 wanted to implement was very expensive, 14 and I needed to have adequate 15 justification to support that system 16 because -- because we did have something 17 in place, so I knew that the feedback I 18 would get is that we were complying with 19 the regulation. So I wanted to show 20 them some of the things that the other 21 companies were doing that DEA 22 categorized as not enough. 23 BY MR. BUCHANAN: 24 Q. Right. I mean, basically, you're</p>	<p style="text-align: right;">Page 277</p> <p>1 down. 2 MR. SCHACK: Thank you. 3 BY MR. BUCHANAN: 4 Q. Okay. All right. So this is 5 suspension order that you tracked, a suspension 6 of a DEA license relating to a Walgreens 7 distribution center in Jupiter, Florida. 8 Do you remember that? 9 A. Yes. 10 Q. Do you remember -- you were aware 11 of that when it happened in 2012, right, as 12 somebody who reads the Federal Register, as 13 somebody who attends DEA conferences? 14 A. Yes. 15 Q. Okay. And then off to the right 16 we see really what you guys were doing, right, 17 and this is your drug that was being shipped in 18 to Florida, right? 19 MS. VANNI: Object to the form. 20 THE WITNESS: I can't read it. 21 BY MR. BUCHANAN: 22 Q. Yeah, it's a challenge with, I 23 don't know, spreadsheets. There's a 24 heading that's --</p>

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<p style="text-align: right;">Page 278</p> <p>1 MR. BUCHANAN: Bradley, I'm 2 sorry, I think it's confusing for people 3 if you do it the way you've done it, 4 because at the top it says "Violation." 5 BY MR. BUCHANAN: 6 Q. Let's just read across the top 7 together, ma'am. You see Violation For -- 8 there's Date, Violation For: Company, Violation, 9 Penalty, a web link, What they did, and What we 10 are doing. 11 Do you see that? 12 A. Yes. 13 Q. Okay. So then there's that 14 reference for the Walgreens facility that we 15 were just looking at, and you see there's a 16 narrative description of what happened with that 17 one? 18 A. Yes. 19 MR. BUCHANAN: And then I need 20 you to blow up, if you could, Bradley, 21 the units all the way to the right. 22 Keep going. Can you make the box a 23 little bigger so we don't clip off the 24 top. Thanks.</p>	<p style="text-align: right;">Page 280</p> <p>1 particular distribution facility that had its 2 license suspended in 2012, correct? 3 A. Yes, looks that way. 4 Q. Of 2009 there were 11 million 5 dosage units, right, Walgreens Jupiter, and you 6 know I think I misspoke. Let me restate this, 7 okay. 8 What's at the top, I believe, are 9 the dosage units shipped into Florida. 10 Do you see that? 11 A. Yes. 12 Q. 83 million dosage units shipped 13 into Florida, right? Am I reading it correctly? 14 A. I can't see. 15 Q. I wish I could do more to help 16 you on that. 17 A. Yes, it states that 83,000 -- 18 83 million doses were sent to Florida in the 19 same time frame. 20 Q. And then in 2009 you shipped 21 11.6 million dosage units to the Jupiter 22 facility of Walgreens, right? 23 A. Yes. 24 Q. In 2010 you shipped 7 million to</p>
<p style="text-align: right;">Page 279</p> <p>1 BY MR. BUCHANAN: 2 Q. Okay. All right. It doesn't get 3 any bigger, but at least it's a little more in 4 focus for you. 5 So what we see here is Walgreens 6 has a situation with their distribution center 7 severe enough that their license is suspended 8 for that particular distribution facility. 9 Do you recall that? 10 A. Yes. 11 Q. Okay. And then what you did is 12 you looked at, hey, what are we doing with them, 13 right? 14 MS. VANNI: Object to form. 15 BY MR. BUCHANAN: 16 Q. Do you see that? 17 A. Mm-hmm. 18 Q. And it shows here that over the 19 same period of time, or I guess really from 20 2009, 2010, 2011, your company, Qualitest 21 shipped how many pills, 83 million pills, right? 22 You see that? 23 A. Yes. 24 Q. Shipped 83 million pills to that</p>	<p style="text-align: right;">Page 281</p> <p>1 that one? 2 A. Yes. 3 Q. And then apparently in 2011 they 4 went to another facility, right? 5 A. Yes. 6 Q. Okay. So over those two years 7 that we have data for, it doesn't go back prior 8 to 2009, there's some, you know, 18 million, 9 19 million, 18 and a half million, I guess to be 10 precise, dosage units of controlled substances 11 going to the facility that the DEA suspended its 12 license in 2012, correct? 13 A. Yes. 14 MS. VANNI: Object to form. 15 BY MR. BUCHANAN: 16 Q. Okay. And the allegation of the 17 DEA was that that facility and the reason for 18 the suspension of a license was that they failed 19 to maintain effective controls against diversion 20 of controlled substances, right? 21 A. Yes. 22 Q. And so prior to -- prior to 2013, 23 ma'am, I take it are you aware of any site 24 visits to Walgreens Jupiter?</p>

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<p style="text-align: right;">Page 282</p> <p>1 A. Again, I don't know what the 2 sales team did, so I don't know if they went to 3 -- went there or not. 4 Q. We know the DEA's conclusion, at 5 least as reflected here, was that they failed to 6 be -- they were not maintaining effective 7 controls against diversion, right? 8 A. Yes. 9 Q. Okay. And had you asked for 10 copies of their suspicious order monitoring 11 protocols prior to 2013? 12 A. Again, I don't know. 13 Q. Okay. I mean, there's a list of 14 violations that are noted over several years in 15 this spreadsheet, correct? 16 A. Yes. 17 Q. For various entities, some are 18 retail pharmacies, some are distributors, 19 correct? 20 A. Yes, mm-hmm. 21 Q. And these are all obviously 22 events that have happened prior to the time of 23 this PowerPoint, right? 24 A. Yes, they are.</p>	<p style="text-align: right;">Page 284</p> <p>1 Do you see that there is 2 information for other entities had their 3 registrations pulled or suspended or there were 4 allegations against with regard to effective 5 controls against diversion on this sheet? 6 MS. VANNI: Object to the 7 colloquy. 8 THE WITNESS: Yes, that's what -- 9 I mean, there are -- that's what this is 10 a list of violations, yes. 11 BY MR. BUCHANAN: 12 Q. There's too many for us to read 13 and it's almost too challenging to put on the 14 screen but -- 15 A. Yes. 16 Q. -- just for the jury's benefit, 17 there are other manufacturers, other 18 distributors, other pharmacies referenced, 19 correct? 20 MS. VANNI: Object to form. 21 THE WITNESS: Yes. 22 BY MR. BUCHANAN: 23 Q. Okay. And there are other areas 24 where it is listed that you are, in fact,</p>
<p style="text-align: right;">Page 283</p> <p>1 Q. And we could agree, couldn't we, 2 ma'am, that you're not aware of any request to 3 any of the entities on this sheet for request 4 for their suspicious order monitoring program or 5 practices prior to the times of these 6 violations, correct? 7 MS. VANNI: Objection. 8 THE WITNESS: I'm not sure. I 9 don't know. 10 BY MR. BUCHANAN: 11 Q. You don't have any information, 12 sitting here today, that you did so? 13 MS. VANNI: Objection. 14 THE WITNESS: Right, or did not. 15 BY MR. BUCHANAN: 16 Q. You have no information either 17 way? 18 A. Correct. 19 Q. Fair enough. Okay. 20 So let's go back to this 21 document. And so tab one was -- I'm sorry, at 22 606.4 we were just looking at violations, what 23 the allegations were, the consequences were and 24 then really where you were shipping product.</p>	<p style="text-align: right;">Page 285</p> <p>1 shipping into that particular customer or 2 community. Do you see the column "What are we 3 doing" on page 606.5 and 606.4? 4 A. I do, yes. 5 Q. And there are other customers 6 that you were, in fact, fulfilling orders for 7 that had their licenses suspended or other 8 consequences? 9 A. Yes. 10 MS. VANNI: Object to form. 11 THE WITNESS: Keep in mind as 12 well that when -- when there is a -- a 13 letter of admonition or issued by DEA 14 for not conducting due diligence, for 15 example, that doesn't mean they're not 16 conducting due diligence on every 17 customer that they have. That means the 18 DEA found an example of that. If the 19 license is getting suspended, they've 20 probably found quite a few of them. 21 However, that license was also 22 reinstated, I believe, at a later date 23 by DEA. So at some point DEA felt that 24 they did have controls and gave them</p>

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<p>1 back their license, basically.  2 BY MR. BUCHANAN:  3 Q. Right. I mean, but the concern,  4 obviously, and you've talked about it in your  5 own writings, we've seen it from the DEA  6 presentation, we have it in your oral testimony  7 today is a closed system, right?  8 A. Yes.  9 MS. VANNI: Object to form.  10 BY MR. BUCHANAN:  11 Q. So if we don't have a closed  12 system at a particular point in time, and I  13 think we looked at that spreadsheet where, I  14 mean, there were billions of pills being made  15 every year of controlled substances by  16 Qualitest, you'd agree?  17 MS. VANNI: Object to form.  18 THE WITNESS: Again, I can't  19 speak to those -- those numbers.  20 BY MR. BUCHANAN:  21 Q. I'll represent to you that the  22 data that's been produced to us reflects that  23 there were billions of pills of controlled  24 substances for hydrocodone and oxycodone that</p>	<p>1 Q. Okay. At 606.14 there's a  2 summary of the current SOMS process.  3 Do you see that?  4 A. Yes, I do.  5 Q. Okay. And this would be the SOMS  6 process for Qualitest as of -- prior to the  7 revamping, right?  8 A. Prior to the upgrades, yes.  9 MS. VANNI: Object to form.  10 BY MR. BUCHANAN:  11 Q. Okay. So the current SOMS  12 process is that -- was really directed at the  13 retail pharmacies, right?  14 MS. VANNI: Object to form.  15 THE WITNESS: Yes.  16 BY MR. BUCHANAN:  17 Q. Okay. So prior to revamping,  18 SOMS procedures and monitoring of the orders was  19 not tied into the wholesale and distributor  20 customers, correct?  21 MS. VANNI: Object to form.  22 THE WITNESS: No, I would  23 disagree with that from the aspect of  24 there was visibility -- in some cases</p>
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<p>1 were being shipped every year, okay, accepting  2 that representation, if a manufacturer -- if  3 anyone in this chain has their head in the sand  4 or isn't doing their job, then we don't have a  5 closed system?  6 MS. VANNI: Object to form.  7 THE WITNESS: Yes, however, a  8 violation from DEA --  9 BY MR. BUCHANAN:  10 Q. That's my question.  11 A. -- a letter of admonition does  12 not mean that somebody had their head in the  13 sand. Again, people make mistakes. Mistakes do  14 occur.  15 Q. Okay, okay. And so when mistakes  16 occur, okay, when there's negligence and --  17 withdrawn.  18 Let's go back to 606.14.  19 This document, again, just to  20 reorient the jury, because we've been hoping  21 around, at 606.1, this is the e-mail from  22 Mr. Shaffer to Mr. Brantley, people obviously in  23 your DEA compliance group, fair?  24 A. Yes.</p>	<p>1 visibility to the inventories at the  2 wholesale level, so I think that  3 there -- they were being monitored, just  4 not part of this process.  5 BY MR. BUCHANAN:  6 Q. Okay. Well, without trying to  7 kind of look backwards and figure out how maybe  8 that could have been done, what was reflected on  9 this particular document, 606.14, as Qualitest's  10 current SOMS practices are these four bullet  11 points, correct?  12 A. Yes.  13 Q. Does the -- does this document  14 describe anything being done with wholesalers?  15 MS. VANNI: Object to form.  16 THE WITNESS: This document does  17 not.  18 BY MR. BUCHANAN:  19 Q. Okay. Retail pharmacies, so one  20 of the items is retail pharmacies under the  21 current SOMS process are based on a product  22 threshold amount, correct?  23 A. Correct.  24 Q. "Retail pharmacy threshold</p>

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<p style="text-align: right;">Page 290</p> <p>1 amounts can be changed by the sales department,"</p> <p>2 right?</p> <p>3 A. Yes.</p> <p>4 Q. And the threshold amounts are set</p> <p>5 by the sales department, right?</p> <p>6 A. Yes.</p> <p>7 Q. And then the system holds the</p> <p>8 order until reviewed, right?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. And so this is the SOMS</p> <p>11 process as memorialized by Qualitest as of this</p> <p>12 point in time, correct?</p> <p>13 A. Correct.</p> <p>14 Q. Okay. The next page sets forth</p> <p>15 the issues with that process, right?</p> <p>16 A. The improvements that we'd like</p> <p>17 to make.</p> <p>18 Q. Well, what's written here is and</p> <p>19 before somebody was asked to testify about it --</p> <p>20 A. Wording.</p> <p>21 Q. Yes, issues with the current</p> <p>22 process, right?</p> <p>23 MS. VANNI: Object to the</p> <p>24 colloquy.</p>	<p style="text-align: right;">Page 292</p> <p>1 Q. Okay. And so as of this point in</p> <p>2 time, as of September 2013, this is some five</p> <p>3 months after your meeting with the DEA, these</p> <p>4 other classes of trades were not evaluated for</p> <p>5 SOMS, correct?</p> <p>6 A. Correct, not through the SOMS</p> <p>7 program. Through the threshold program.</p> <p>8 Q. We can agree that the people in</p> <p>9 the DEA compliance group who are at this point</p> <p>10 in time trying to respond to criticisms and</p> <p>11 concerns concerning the SOMS program are</p> <p>12 identifying issues with the process, right?</p> <p>13 MS. VANNI: Object to form.</p> <p>14 THE WITNESS: We're saying what's</p> <p>15 wrong with the current process in order</p> <p>16 to get improvements made.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Okay. Well, I mean, it wasn't</p> <p>19 false when they wrote it, was it? They wouldn't</p> <p>20 be lying to their boss about it, right?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: No.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Okay. So we can agree that these</p>
<p style="text-align: right;">Page 291</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Okay. Issues with the process.</p> <p>4 The current "system only addresses retail</p> <p>5 pharmacy by looking at product thresholds."</p> <p>6 Do you see that?</p> <p>7 A. I do.</p> <p>8 Q. "Other COTs are not evaluated for</p> <p>9 SOMS."</p> <p>10 Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. Other classes of trade, that's</p> <p>13 what COTs means right?</p> <p>14 A. Yes, it is.</p> <p>15 Q. And you broke down for us earlier</p> <p>16 what classes of trades are, right?</p> <p>17 A. Yes.</p> <p>18 Q. Classes of trades could be</p> <p>19 distributors and wholesalers, right?</p> <p>20 A. Yes.</p> <p>21 Q. Hospitals, right?</p> <p>22 A. Yes.</p> <p>23 Q. What were the other big ones?</p> <p>24 A. Clinics, long-term care.</p>	<p style="text-align: right;">Page 293</p> <p>1 were, in fact, issues with the then current</p> <p>2 process prior to the revamping of the system in</p> <p>3 2013, right?</p> <p>4 A. They were gaps that we internally</p> <p>5 wanted to improve upon.</p> <p>6 Q. Right, I mean, look, especially</p> <p>7 if you're selling 33 billion pills of</p> <p>8 hydrocodone, it's a pretty big gap not to be</p> <p>9 looking at wholesalers and distributors for</p> <p>10 SOMS, right?</p> <p>11 MS. VANNI: Objection.</p> <p>12 THE WITNESS: Really the</p> <p>13 wholesalers and distributors are not --</p> <p>14 they weren't the problem. The retail</p> <p>15 pharmacies were the problem.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Right, but --</p> <p>18 A. So we were glad that we were</p> <p>19 looking at retail pharmacies versus wholesalers.</p> <p>20 Q. Well, you knew from the DEA back</p> <p>21 all the way for years -- when you were at</p> <p>22 Watson, you were looking at wholesalers?</p> <p>23 A. They look at wholesalers on the</p> <p>24 sale side separate from SOMS. If they weren't</p>

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<p style="text-align: right;">Page 294</p> <p>1 looking at the quantities they were sending to</p> <p>2 wholesalers, they would be sending all their</p> <p>3 product to one wholesaler and that could cause</p> <p>4 problems. It's more from an order management</p> <p>5 system, that's why it's not detailed in SOMS.</p> <p>6 Q. Well, we know from this that an</p> <p>7 issue before somebody who was asked to testify</p> <p>8 about it with the current process was that other</p> <p>9 classes of trades were not being evaluated for</p> <p>10 SOMS, right?</p> <p>11 MS. VANNI: Objection.</p> <p>12 THE WITNESS: Other classes of</p> <p>13 trades were not part of the SOMS</p> <p>14 program.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. What this writes --</p> <p>17 A. They were part of OMS, which is</p> <p>18 not what this document is talking about.</p> <p>19 Q. The way this is written, ma'am,</p> <p>20 is other classes of trades are not evaluated for</p> <p>21 SOMS. That's the way it's written, correct?</p> <p>22 MS. VANNI: Object to form.</p> <p>23 THE WITNESS: That is the way</p> <p>24 it's written.</p>	<p style="text-align: right;">Page 296</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And so compliance can be</p> <p>3 bad for dollars or compliance can be bad for</p> <p>4 sales, right?</p> <p>5 MS. VANNI: Object to form.</p> <p>6 THE WITNESS: I'm sorry? What</p> <p>7 did you say?</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. Compliance can be bad for dollars</p> <p>10 and it can be bad for sales, right?</p> <p>11 MS. VANNI: Objection.</p> <p>12 THE WITNESS: There is a cost to</p> <p>13 compliance, yes.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Further issue with the current</p> <p>16 process is that once a customer hit their</p> <p>17 threshold, they could just call up or send an</p> <p>18 e-mail and request a threshold increase, right?</p> <p>19 A. Yes.</p> <p>20 Q. Hey, I know we hit our cap last</p> <p>21 month, we need more, right?</p> <p>22 MS. VANNI: Object to form.</p> <p>23 THE WITNESS: Not without</p> <p>24 justifiable reason.</p>
<p style="text-align: right;">Page 295</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. What are SOMS, suspicious order</p> <p>3 monitoring?</p> <p>4 A. That's what the system is, yes.</p> <p>5 Q. "Retail pharmacy review and</p> <p>6 approval is handled by the sales department,"</p> <p>7 right?</p> <p>8 A. Yes.</p> <p>9 Q. And you knew from the DEA that's</p> <p>10 not good, right?</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: Yes, that's not</p> <p>13 what DEA wanted to see, not required by</p> <p>14 the regulation, but not what they wanted</p> <p>15 to see.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Well, and the DEA viewed this as</p> <p>18 a conflict of interest and considered the sales</p> <p>19 department as the department that is driven by</p> <p>20 what?</p> <p>21 A. Driven by dollars.</p> <p>22 Q. Driven by sales?</p> <p>23 A. Mm-hmm.</p> <p>24 Q. Right?</p>	<p style="text-align: right;">Page 297</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Right, the sales department was</p> <p>3 handling the threshold increases, right?</p> <p>4 A. Yes.</p> <p>5 Q. That was one of the issues with</p> <p>6 the current process as framed out in this</p> <p>7 October 2013 presentation, right?</p> <p>8 A. And, again, our sales department,</p> <p>9 we had people who had good integrity, and it</p> <p>10 wasn't an issue that it was part of the sales</p> <p>11 department, with the exception of the</p> <p>12 perception.</p> <p>13 Q. And that's something that you</p> <p>14 hope but cannot know, ma'am?</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: It's something that</p> <p>17 I did know based on the calls that were</p> <p>18 made to me and the questions that were</p> <p>19 asked.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Okay. We know that you did not</p> <p>22 visit or your sales team didn't visit every</p> <p>23 customer, right?</p> <p>24 A. Don't know that. I wasn't there.</p>

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1 Q. We know after some visits started  
2 to occur that you did find some of those  
3 pharmacies like the pictures we looked at,  
4 right?

5 MS. VANNI: Object to form.

6 THE WITNESS: Don't know about  
7 that, but...

8 BY MR. BUCHANAN:

9 Q. [REDACTED]

13 Q. Pharmacies that you had to cut  
14 off?

15 MS. VANNI: Object to form.

16 THE WITNESS: Pharmacies -- there  
17 were customers that we reported to DEA,  
18 I'm sure.

19 BY MR. BUCHANAN:

20 Q. There were customers after you  
21 implemented a revised SOMS program that you had  
22 to cut off, right?

23 A. I believe so.

24 Q. Are you aware of any customer

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1 Do you see that, ma'am?

2 A. Yes.

3 Q. And that was an issue with the  
4 current process as of October 2013?

5 A. The system didn't stop an order  
6 because of an out of frequency or out of  
7 pattern. However, part of looking at a  
8 threshold quantity is to look at the history of  
9 the account, which would give you the order  
10 frequency and pattern. So it wasn't picked up  
11 by the system automatically, but it was  
12 reviewed.

13 Q. Well, as of this point in time,  
14 we know you weren't reviewing other classes of  
15 trade, right?

16 A. We were not as part of SOMS.

17 Q. We know, at least what's written  
18 here, ma'am, is that there was "no check for  
19 order frequency and pattern discrepancies,"  
20 correct?

21 A. Not by the initial electronic  
22 system.

23 Q. Not by the system that could be  
24 reviewing the thousands and thousands of orders

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1 that you cut off in the two years prior to  
2 implementing the new SOMS program?

3 A. None that I can name, but I know  
4 that there were some then as well.

5 Q. Sitting here today, can you name  
6 one?

7 A. I cannot.

8 Q. It states that there was "no  
9 separate/unbiased check of order quantity  
10 outside of the sales and marketing departments."

11 Do you see that?

12 A. Yes.

13 Q. There was no unbiased check of  
14 the orders outside of the sales and marketing  
15 group, that was an issue with the current  
16 process as of October 2014, correct, ma'am --  
17 2013, correct?

18 MS. VANNI: Object to form.

19 THE WITNESS: I'm not quite sure  
20 what that bullet means actually at this  
21 point, but that's what it says, yes.

22 BY MR. BUCHANAN:

23 Q. "No check for order frequency and  
24 pattern discrepancies."

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1 or line items that a company is getting, right?

2 MS. VANNI: Object to form.

3 THE WITNESS: No, the system  
4 would have been reviewing those line  
5 items, but it would have been stopping  
6 the orders based on quantity, and then  
7 after quantity, after the orders stopped  
8 based on quantity, it would have been  
9 reviewed for pattern and frequency.

10 BY MR. BUCHANAN:

11 Q. Okay. Well, we know as of this  
12 point in time, certainly what's stated here is  
13 there was no check for order frequency and  
14 pattern discrepancy, that's what was written by  
15 your colleagues in the DEA compliance group,  
16 correct?

17 A. By the electronic system.

18 Q. That does not say that; can we  
19 agree on that?

20 MS. VANNI: Object to form.

21 THE WITNESS: That's how you're  
22 interpreting it, so...

23 BY MR. BUCHANAN:

24 Q. Well, I'm asking can we agree it

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<p style="text-align: right;">Page 302</p> <p>1 doesn't say what you just said?</p> <p>2 A. It does not say.</p> <p>3 Q. Thank you. It says the "system</p> <p>4 does not allow for" what?</p> <p>5 A. "Know Your Customer."</p> <p>6 Q. Okay. And so the "Requirements</p> <p>7 for Improvement" are listed on the next page,</p> <p>8 right?</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. These are things you have to do,</p> <p>12 right?</p> <p>13 MS. VANNI: Object to form.</p> <p>14 THE WITNESS: Things we wanted to</p> <p>15 do.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. It says requirements, right?</p> <p>18 A. Things we want to do. It's a</p> <p>19 play on words but...</p> <p>20 Q. Well, okay. What's written here</p> <p>21 while you're -- before somebody was sitting in</p> <p>22 this seat to reinterpret the words was</p> <p>23 "Requirements for Improvement," agreed?</p> <p>24 MS. VANNI: Object to form.</p>	<p style="text-align: right;">Page 304</p> <p>1 is above the regulation.</p> <p>2 Q. Okay. Something a responsible</p> <p>3 company should do, right?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 THE WITNESS: Possibly, yes.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. I mean, you list it as a</p> <p>8 requirement, right?</p> <p>9 A. Right, another example of</p> <p>10 something that's not a requirement but that's</p> <p>11 listed, yes.</p> <p>12 Q. Okay. I guess if you're going to</p> <p>13 make a promise to maintain effective controls of</p> <p>14 diversion, you should do whatever you can do to</p> <p>15 make sure these things don't leave the channel</p> <p>16 of trade, right?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. And stay in the closed system,</p> <p>21 yes?</p> <p>22 MS. VANNI: Object to form.</p> <p>23 THE WITNESS: Yes.</p> <p>24 BY MR. BUCHANAN:</p>
<p style="text-align: right;">Page 303</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Thank you.</p> <p>4 The first bullet as a requirement</p> <p>5 is a system to look at all class of trades and</p> <p>6 customers.</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And the classes of trades and</p> <p>10 customers are wholesalers, distributors,</p> <p>11 manufacturers, et cetera, right?</p> <p>12 A. Yes.</p> <p>13 Q. Not just look at pharmacies or</p> <p>14 retail pharmacies, right?</p> <p>15 A. To include these other customers</p> <p>16 as part of SOMS, yes.</p> <p>17 Q. A system to look at all classes</p> <p>18 of trades and customers.</p> <p>19 Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. Okay. A system to look at all</p> <p>22 controlled substances.</p> <p>23 Do you see that?</p> <p>24 A. Yes, and listed chemicals, which</p>	<p style="text-align: right;">Page 305</p> <p>1 Q. Thank you.</p> <p>2 It says, and there's a number of</p> <p>3 items here, but I'm getting notes that I need to</p> <p>4 move more quickly. Let's head down to the third</p> <p>5 bullet from the bottom.</p> <p>6 You see that, requirement for</p> <p>7 improvement, "Access to chargeback data and 3rd</p> <p>8 party data i.e. IMS."</p> <p>9 Do you see that?</p> <p>10 A. Yes, I do.</p> <p>11 Q. Okay. So one of the requirements</p> <p>12 for improvement was implementing chargeback data</p> <p>13 as part of your process, right?</p> <p>14 A. One of the things we wanted to</p> <p>15 do, yes.</p> <p>16 Q. Okay. And you say "wanted," this</p> <p>17 says requirements, right?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: The document says</p> <p>20 requirements. That's not what this is,</p> <p>21 but yes.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. Okay. And then -- well, you were</p> <p>24 also told by the DEA in your meeting, you got to</p>

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<p style="text-align: right;">Page 306</p> <p>1 start looking at chargeback data, right?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: It's not a</p> <p>4 regulation.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Well, didn't they tell you you</p> <p>7 need to do that?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: They said you</p> <p>10 should look at it. There's a difference</p> <p>11 between should and must.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. Okay. And you'd agree, ma'am, as</p> <p>14 a company that has been given a permission slip</p> <p>15 by the U.S. government to stamp apparently</p> <p>16 billions of pills every year, that you've got to</p> <p>17 act consistent with the terms of that permission</p> <p>18 slip, right?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: Yes, with the</p> <p>21 regulations.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. And the law, the statute, right?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 308</p> <p>1 particular product lines, right?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: It's one piece of a</p> <p>4 -- of an investigation, yes.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Okay. We see in this next page</p> <p>7 -- I'm sorry -- 1000 -- 606.18.</p> <p>8 We saw a memo from Mr. Rannazzisi</p> <p>9 or to Mr. Rannazzisi relating to your DEA</p> <p>10 interaction in March of 2013.</p> <p>11 Do you remember that? Ma'am, I'm</p> <p>12 probably confusing you by showing you the page</p> <p>13 first.</p> <p>14 Do you remember we were just</p> <p>15 looking at a memo to Mr. Rannazzisi from the DEA</p> <p>16 officer who was at the meeting you were in in</p> <p>17 March of 2013?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. In this presentation, it</p> <p>20 says "DEA's Attempted Elucidation of SOMS</p> <p>21 Requirement."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. And this is a 2007 letter from</p>
<p style="text-align: right;">Page 307</p> <p>1 Q. Which says you must maintain</p> <p>2 effective controls against diversion, right?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And so one of the tools of</p> <p>5 information -- one of the classes of information</p> <p>6 available to manufacturers for many of its</p> <p>7 customers is chargeback data, right?</p> <p>8 A. That's what DEA believes, yes.</p> <p>9 Q. Another category of information</p> <p>10 that's available to manufacturers is IMS data,</p> <p>11 right?</p> <p>12 A. Yes.</p> <p>13 Q. And using IMS data, you can see</p> <p>14 in percentage terms quantities that end user</p> <p>15 pharmacies might be acquiring, whether they're</p> <p>16 consistent with national averages, whether</p> <p>17 they're above national averages or whether</p> <p>18 they're below, right?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. And that can raise red flags as</p> <p>23 to whether a pharmacy, for example, is above</p> <p>24 what you know the national average to be for</p>	<p style="text-align: right;">Page 309</p> <p>1 the DEA to you, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And you were aware of this</p> <p>4 document, correct?</p> <p>5 MS. VANNI: Object -- just --</p> <p>6 when you say "you," that's vague and</p> <p>7 ambiguous, and she wasn't at the company</p> <p>8 at the time in 2007.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Well, I mean, this is a</p> <p>11 PowerPoint from -- this is a PowerPoint from</p> <p>12 2013, correct, ma'am?</p> <p>13 A. Yeah, but this is just including,</p> <p>14 I think, the general letter that DEA sent out to</p> <p>15 registrants. I have to read it to see.</p> <p>16 Q. Oh, okay. Let me but -- do you</p> <p>17 recall that the DEA sent out a letter to</p> <p>18 registrants in 2007?</p> <p>19 A. Yes.</p> <p>20 Q. You were working at a registrant</p> <p>21 at that point in time?</p> <p>22 A. Yes.</p> <p>23 Q. You got a copy of it while you</p> <p>24 were at that company, right?</p>

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<p style="text-align: right;">Page 310</p> <p>1 A. Every entity, so, yes, that's</p> <p>2 what this is.</p> <p>3 Q. Okay. So this is a letter from</p> <p>4 DEA to the company in 2007 saying you've got</p> <p>5 obligations, you've got to maintain effective</p> <p>6 controls against diversion, you've got to have</p> <p>7 suspicious order monitoring systems, a routine</p> <p>8 threshold is not enough, you've got to do more,</p> <p>9 right?</p> <p>10 MS. VANNI: Object to form.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. Okay. And I just was -- I just</p> <p>14 wanted to confirm that, you know, you were</p> <p>15 certainly aware of that letter as of 2013, but</p> <p>16 it sounds like you were aware of the equivalent</p> <p>17 letter from your prior work with other</p> <p>18 manufacturers, correct?</p> <p>19 A. Yes, yes, I was, mm-hmm.</p> <p>20 Q. Okay. So you know the DEA had</p> <p>21 spoken about this certainly prior to 2013?</p> <p>22 A. Yes.</p> <p>23 Q. And you had obviously had that</p> <p>24 sit-down you had with Watson and Anda prior to</p>	<p style="text-align: right;">Page 312</p> <p>1 THE VIDEOGRAPHER: Going off the</p> <p>2 record. The time now is 2:02 p.m.</p> <p>3 (Brief recess.)</p> <p>4 (Document marked for</p> <p>5 identification as Par-Norton Deposition</p> <p>6 Exhibit No. 13.)</p> <p>7 THE VIDEOGRAPHER: We're now</p> <p>8 going back on the record. The time is</p> <p>9 2:24 p.m.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Ma'am, I'm passing you over</p> <p>12 another exhibit in this 2013 period. This one</p> <p>13 is from March of 2013. Looks like it's a</p> <p>14 PowerPoint that you put together for a meeting</p> <p>15 you were going to have?</p> <p>16 A. Mm-hmm.</p> <p>17 Q. You see March 13, 2013, it's</p> <p>18 E581, and we've marked it as Exhibit 13 to your</p> <p>19 deposition.</p> <p>20 A. Okay.</p> <p>21 Q. You forward it to a distribution</p> <p>22 list Ms. Hudson, Ms. Bigelow -- I'm sorry --</p> <p>23 Mr. Bigelow, Mr. Propst, Sanjay Patel, Margaret</p> <p>24 Richardson, Mike Reiney and Jill Connell, cc'd</p>
<p style="text-align: right;">Page 311</p> <p>1 that, right?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. So this is a letter that's</p> <p>4 being called out to the attention of -- in the</p> <p>5 PowerPoint from 2007 from Mr. Rannazzisi.</p> <p>6 Then you also identify examples</p> <p>7 of repercussions.</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. And this is again -- was this</p> <p>11 part of trying to get that kind of management</p> <p>12 buy-in to -- whether it was increase head count</p> <p>13 or increase budget to improve the SOM system?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: And education, yes.</p> <p>16 MS. VANNI: Counsel, when you get</p> <p>17 a normal stopping break, can we just</p> <p>18 have a break, use the ladies room.</p> <p>19 MR. BUCHANAN: That's fine. I</p> <p>20 may be just about done with this</p> <p>21 document.</p> <p>22 MS. VANNI: That's fine.</p> <p>23 MR. BUCHANAN: It's good. We can</p> <p>24 go off the record.</p>	<p style="text-align: right;">Page 313</p> <p>1 Sue Dear and Patricia Simmet.</p> <p>2 You see that?</p> <p>3 A. Yes.</p> <p>4 Q. Slide deck for this morning's</p> <p>5 meeting, right?</p> <p>6 A. Mm-hmm.</p> <p>7 Q. Is this your group and people</p> <p>8 that are in management either aligned with your</p> <p>9 group or they could be affected by what you're</p> <p>10 being -- what you're proposing?</p> <p>11 A. It's not my group, it's the</p> <p>12 management team.</p> <p>13 Q. I see. This was --</p> <p>14 A. Some of the management team.</p> <p>15 Q. So this is some folks from your</p> <p>16 group and some folks from the management team?</p> <p>17 A. Yes.</p> <p>18 Q. Or just the management team?</p> <p>19 A. When you say "my group," my boss</p> <p>20 and boss's boss, yes.</p> <p>21 Q. Okay. But not those who worked</p> <p>22 for you?</p> <p>23 A. Correct.</p> <p>24 Q. Understood.</p>

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<p style="text-align: right;">Page 314</p> <p>1 So this is kind of a high level 2 deck, right? 3 MS. VANNI: Object to form. 4 THE WITNESS: Yes. 5 BY MR. BUCHANAN: 6 Q. High level meeting? 7 A. Mm-hmm. 8 Q. That's yes? 9 A. Yes. 10 MS. VANNI: I'll objection to 11 form. 12 BY MR. BUCHANAN: 13 Q. So after you get back from the 14 DEA in March of 2013, we saw your e-mail where 15 you did some quick thoughts, we've seen the 16 DEA's kind of summary of that meeting and 17 Ms. Hudson's summary of that meeting. 18 You recall us discussing that 19 today? 20 A. Yes. 21 Q. Okay. And this is your 22 PowerPoint that you put together for the 23 management team, right? 24 A. Yes.</p>	<p style="text-align: right;">Page 316</p> <p>1 Reporting," right? 2 A. Correct. 3 Q. Another is "Manufacturing Site 4 Compliance," right? 5 A. Yes. 6 Q. This is vaults and fences and 7 monitors and making sure two people are watching 8 at all times, that type of stuff? 9 MS. VANNI: Object to form. 10 THE WITNESS: Yes. 11 BY MR. BUCHANAN: 12 Q. There's this "Quota Grant 13 Process" on the left, top left, do you see that? 14 That's a component of DEA 15 compliance, right? 16 A. Yes, it is. 17 Q. Okay. Making sure that you're 18 only asking what you need for legitimate medical 19 purposes, right? 20 MS. VANNI: Object to form. 21 THE WITNESS: Correct. 22 BY MR. BUCHANAN: 23 Q. And because, frankly, your quotas 24 are supposed to be based on what's needed for</p>
<p style="text-align: right;">Page 315</p> <p>1 Q. Okay. And DEA SOMS action plan, 2 right? 3 A. Mm-hmm. 4 Q. March 13, 2013? 5 A. Yes. 6 Q. And this was something you put 7 together? 8 A. Yes, Sanjay had some input into 9 it as well, my boss. 10 Q. Your boss did, okay. 11 Was your boss at the meeting? 12 A. At the DEA meeting, I think he -- 13 he was not, but I think he was supposed to be 14 originally. I think he was missed because of 15 the snow. 16 Q. Okay. And on this slide it says 17 "Core Elements of DEA Compliance Team," and then 18 there's this kind of chart in the middle, kind 19 of a working framework for your presentation, 20 "Critical Elements of DEA Compliance." 21 Do you see that? 22 A. Yes. 23 Q. And one of the critical elements 24 of DEA compliance is "Data Integrity &amp;</p>	<p style="text-align: right;">Page 317</p> <p>1 legitimate medical use, right? 2 MS. VANNI: Object to form. 3 THE WITNESS: Yes. 4 BY MR. BUCHANAN: 5 Q. Okay. And then there's this 6 component off to the right, as a critical 7 element of DEA compliance "Suspicious Order 8 Monitoring," correct? 9 A. Correct. 10 Q. So -- 11 A. Excuse me. May I just go back to 12 the quota process? 13 Q. If I could move forward, I am 14 time limited. If it's important enough, feel 15 free to discuss with your counsel, and she'll 16 call it out on direct. 17 A. Okay. 18 Q. Suspicious order monitoring and 19 we've spent some time talking about that today, 20 right? 21 A. Yes. 22 Q. And what it says here is a 23 critical element of DEA compliance is to 24 "Implement a solution that proactively discloses</p>

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<p style="text-align: right;">Page 318</p> <p>1 suspicious orders based on unusual size, order 2 pattern, deviation and unusual frequency," 3 correct? 4 A. That's what it says, yes. 5 Q. And then the DEA SOMS feedback 6 you got on the next page, 581.6, was that "You 7 need to differentiate between the sales team 8 role and the DEA compliance role", right? 9 A. Yes, that's what it says. 10 Q. "You need to visit your 11 customers," right, and then this is an 12 exclamation point, right? 13 MS. VANNI: Object to form. 14 THE WITNESS: That's what it 15 says, yes. 16 BY MR. BUCHANAN: 17 Q. You got to put boots on the 18 ground from compliance with customers, right? 19 MS. VANNI: Object to form. 20 THE WITNESS: Yes, that's what 21 DEA would like to see. 22 BY MR. BUCHANAN: 23 Q. I'm assuming you put an 24 exclamation point in there for emphasis, right?</p>	<p style="text-align: right;">Page 320</p> <p>1 Q. And that was one of your 2 takeaways from this meeting with the DEA, right? 3 MS. VANNI: Object to form. 4 THE WITNESS: Yes, it was one of 5 their feedback points. 6 BY MR. BUCHANAN: 7 Q. And the reference to you there, 8 as you're kind of rephrasing and recasting what 9 happened at the DEA meeting, was Qualitest, 10 Qualitest needs to use the chargeback data to 11 understand what Qualitest customers' customers 12 are doing, right? 13 MS. VANNI: Object to form. 14 THE WITNESS: Yes, that was a 15 suggestion by DEA, yes. 16 BY MR. BUCHANAN: 17 Q. And the way you framed it is you 18 need to, right? 19 A. I'm just documenting what DEA 20 told us during the meeting. 21 Q. Right. 22 And in terms of further 23 documenting what the DEA told you, the DEA told 24 you you must know the customers you are selling</p>
<p style="text-align: right;">Page 319</p> <p>1 A. Yes. 2 Q. Okay. We have a problem, I guess 3 "we" there is the DEA -- are you using we to 4 refer to the DEA? 5 A. We to refer to our company. 6 Q. Well, it says, we have a problem 7 with companies using their sales team to conduct 8 these site visits. 9 A. Oh, I'm sorry, it is DEA. 10 Q. In that instance, you were using 11 the term we to refer to the DEA? 12 A. Yes. 13 Q. Right, and you understood the DEA 14 had a problem with companies using sales teams 15 to conduct the site visits, right? 16 MS. VANNI: Object to form. 17 THE WITNESS: They had a concern, 18 yes. 19 BY MR. BUCHANAN: 20 Q. Then it says you need to use the 21 chargeback data to understand what your 22 customers' customers are doing. 23 Did I read that correctly? 24 A. Yes.</p>	<p style="text-align: right;">Page 321</p> <p>1 to, right? 2 A. Yes. 3 Q. "You need to track your product 4 from the time it is manufactured to when it is 5 sold to the patient." 6 Did I read that correctly? 7 A. To the best of your ability. 8 Yes, you did read it correctly. 9 Q. The way you wrote it was, and you 10 didn't put to the best of your ability, but the 11 way you wrote it was you need to track your 12 product from the time it is manufactured to when 13 it is sold to the patient, correct? 14 MS. VANNI: Object to form. 15 THE WITNESS: Yes, that's how 16 it's written. 17 BY MR. BUCHANAN: 18 Q. "Need to have the best possible 19 systems to know what is happening with your 20 product," right? 21 A. That's what it says, yes. 22 Q. That's what you wrote. 23 And this was your DEA feedback 24 that you were recounting to senior management at</p>

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<p style="text-align: right;">Page 322</p> <p>1 Qualitest, correct?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: Correct.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. You "need to have a good SOM</p> <p>6 program that is adequate for the business you</p> <p>7 are in," right?</p> <p>8 A. Yes, that's what it says.</p> <p>9 Q. Okay. Then says "look at the</p> <p>10 charts provided," and I guess you're saying that</p> <p>11 was what the DEA told you, look at the charts</p> <p>12 provided, right?</p> <p>13 A. Yes.</p> <p>14 Q. Remember we looked at those</p> <p>15 graphs that had vintage and Generic Bidco, I</p> <p>16 think was the other one?</p> <p>17 A. Yes, we did.</p> <p>18 Q. Okay. Those were the charts you</p> <p>19 got from the DEA?</p> <p>20 A. Yes.</p> <p>21 Q. All right. And so you're saying</p> <p>22 the DEA told you to look at the charts provided</p> <p>23 and we will visit your site and we will want to</p> <p>24 see improvements in when?</p>	<p style="text-align: right;">Page 324</p> <p>1 right?</p> <p>2 A. Yes, that's what it says.</p> <p>3 Q. That's what you wrote?</p> <p>4 A. Yes. It's all things that DEA</p> <p>5 commented on or suggested during their meeting.</p> <p>6 Q. Right. I mean, all things that</p> <p>7 you thought were important enough to relay to</p> <p>8 senior management, correct?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Okay. Further, that "You need to</p> <p>13 visit your customer's customers and document</p> <p>14 your findings," right?</p> <p>15 A. Yes.</p> <p>16 Q. That's what it says?</p> <p>17 A. That's what it says.</p> <p>18 Q. Not just your customers, right?</p> <p>19 A. It says "your customer's</p> <p>20 customers."</p> <p>21 Q. Right. So you need to visit not</p> <p>22 just your customers but your customers'</p> <p>23 customers, right?</p> <p>24 MS. VANNI: Object to form.</p>
<p style="text-align: right;">Page 323</p> <p>1 A. In six months.</p> <p>2 Q. Right. In six months.</p> <p>3 So we've been looking at some</p> <p>4 dialogue that was happening in October,</p> <p>5 September of 2013.</p> <p>6 You recall that?</p> <p>7 A. Yes.</p> <p>8 Q. You brought Mr. Brantley in in</p> <p>9 September of 2013, roughly about six months</p> <p>10 after this, right?</p> <p>11 A. Yes.</p> <p>12 Q. You sent your dear customer</p> <p>13 letter out in mid-October of 2013, right?</p> <p>14 A. Yes.</p> <p>15 Q. And you sat down with the DEA</p> <p>16 again couple weeks after your dear customer</p> <p>17 letter went out, right?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: Yes, I believe so.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Okay. "We will not look the</p> <p>22 other way if someone screws up. Possible</p> <p>23 actions include suspension or revocation of</p> <p>24 license, civil and criminal ramifications,"</p>	<p style="text-align: right;">Page 325</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. And document your findings; is</p> <p>4 that right?</p> <p>5 A. Yes, which would not be</p> <p>6 permitted.</p> <p>7 Q. And you -- I'm sorry?</p> <p>8 A. Which would not be permitted.</p> <p>9 You can't visit your customers' customers.</p> <p>10 They're not your customer.</p> <p>11 Q. You can go to any pharmacy you</p> <p>12 want and walk into, right?</p> <p>13 A. Not to do a SOM visit, not to ask</p> <p>14 questions about their business and their</p> <p>15 program. That's your customer's job to ask</p> <p>16 questions about their customer. So you can't</p> <p>17 skip a line -- a link in the supply chain and go</p> <p>18 to that next level --</p> <p>19 Q. Well, we can agree you didn't</p> <p>20 tell the DEA that in March 2013, did you, ma'am?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: We didn't get into</p> <p>23 that level of detail in the</p> <p>24 conversation.</p>

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<p style="text-align: right;">Page 326</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Right, and what the --</p> <p>3 A. We were more listening.</p> <p>4 Q. What the DEA told you was you</p> <p>5 need to visit your customers' customers and</p> <p>6 document your findings, right?</p> <p>7 A. That's what the document says,</p> <p>8 yes.</p> <p>9 Q. And "you must provide documented</p> <p>10 evidence of these assessments," right?</p> <p>11 A. Yes, and, again, none of this is</p> <p>12 in the regulations.</p> <p>13 Q. Ma'am, just stay with my</p> <p>14 questions, okay.</p> <p>15 A. Yes.</p> <p>16 Q. We could agree this is what you</p> <p>17 were told to do, correct?</p> <p>18 MS. VANNI: Object to the form.</p> <p>19 THE WITNESS: This is -- these</p> <p>20 are the suggestions we received, the</p> <p>21 feedback we received at that meeting.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. Well, you're saying suggestions.</p> <p>24 It says you need to, right?</p>	<p style="text-align: right;">Page 328</p> <p>1 received, right, "you cannot sell," correct?</p> <p>2 MS. VANNI: Object to the form.</p> <p>3 THE WITNESS: That was the</p> <p>4 feedback we received, yes.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. You must alert us of suspicious</p> <p>7 orders, right?</p> <p>8 A. Yes.</p> <p>9 Q. And if you don't adhere to your</p> <p>10 responsibilities, and, again, everything that</p> <p>11 we've just identified was information you</p> <p>12 received from DEA at that meeting, right?</p> <p>13 A. Yes.</p> <p>14 Q. And here you say, "If you fail to</p> <p>15 adhere to your responsibilities," you understood</p> <p>16 these to be your responsibilities, right?</p> <p>17 MS. VANNI: Object to the form.</p> <p>18 THE WITNESS: It's your</p> <p>19 responsibility to comply to the</p> <p>20 regulation.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. What you wrote here is, "If you</p> <p>23 fail to adhere to your responsibilities," and we</p> <p>24 could agree that above that is one, two, three,</p>
<p style="text-align: right;">Page 327</p> <p>1 A. If we needed to, there would have</p> <p>2 been a violation coming as a result of not</p> <p>3 having it.</p> <p>4 Q. Well, let's not recast. How did</p> <p>5 you write it?</p> <p>6 MS. VANNI: Object to the</p> <p>7 colloquy.</p> <p>8 THE WITNESS: It's written as the</p> <p>9 feedback that we received from the DEA.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Let's stay on this bullet, ma'am.</p> <p>12 What did you write, "you need to"?</p> <p>13 A. "You need to visit your</p> <p>14 customer's customers and document your</p> <p>15 findings."</p> <p>16 Q. Next sentence.</p> <p>17 A. You must.</p> <p>18 Q. You must, must, right?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. Next "you cannot sell the</p> <p>21 products until you have satisfactorily closed</p> <p>22 out the investigation," right?</p> <p>23 A. Yes.</p> <p>24 Q. That was the information you</p>	<p style="text-align: right;">Page 329</p> <p>1 four, five, six, seven, eight, nine items, and</p> <p>2 the jury will have the document, but there's</p> <p>3 nine items where you identified you need to, we</p> <p>4 must, you need to, you must know, you need to</p> <p>5 have the best possible, you need to have a good</p> <p>6 SOM program, we will visit your site to confirm</p> <p>7 improvements, we will not look the other way,</p> <p>8 you need to visit, need, need, need,</p> <p>9 requirements, right?</p> <p>10 MS. VANNI: Object to form.</p> <p>11 THE WITNESS: These are all</p> <p>12 things that DEA suggested during the</p> <p>13 meeting.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. "If you fail to adhere to your</p> <p>16 responsibilities, you present" what, ma'am?</p> <p>17 A. "A danger to the public," that</p> <p>18 was words from DEA.</p> <p>19 Q. Okay. Closed system, right?</p> <p>20 A. Yes.</p> <p>21 Q. Your obligation to maintain a</p> <p>22 closed system, right?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 THE WITNESS: To abide by the</p>

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<p>1 regulations and maintain.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. To maintain a closed system?</p> <p>4 A. Yes, and we did.</p> <p>5 Q. Move to strike, ma'am. Stay with</p> <p>6 my question.</p> <p>7 Your obligation, I'm not asking</p> <p>8 what happened. Somebody else will decide</p> <p>9 whether it complied or didn't comply.</p> <p>10 A. Yes.</p> <p>11 Q. Your obligation is to maintain</p> <p>12 that closed system, correct?</p> <p>13 MS. VANNI: Object to form.</p> <p>14 THE WITNESS: Yes.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Your obligation in maintaining</p> <p>17 that closed system is to sell to people who,</p> <p>18 based on your due diligence and investigation,</p> <p>19 will likewise maintain that closed system,</p> <p>20 right?</p> <p>21 A. Yes.</p> <p>22 Q. And to conduct due diligence to</p> <p>23 assure that their customers have processes in</p> <p>24 place to maintain the closed system, correct?</p>	<p>1 information can't be discerned, if you can't go</p> <p>2 and visit a facility, if you can't look at</p> <p>3 chargeback data, I mean, all you can do is your</p> <p>4 best, right?</p> <p>5 A. Correct.</p> <p>6 Q. But you've got to try to do your</p> <p>7 best, right?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Okay. "People are dying; kids</p> <p>12 are born addicted."</p> <p>13 You see that?</p> <p>14 A. Yes.</p> <p>15 Q. That was a true statement</p> <p>16 certainly as of 2013, right?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. "These people would not have the</p> <p>21 drugs if it weren't for the manufacturers and</p> <p>22 distributors."</p> <p>23 Do you see that?</p> <p>24 A. That's what DEA said.</p>
Page 331	Page 333
<p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: The suggestion is</p> <p>3 to know your customer. The suggestion</p> <p>4 is not to know your customer's customer.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. It's not a suggestion, ma'am.</p> <p>7 What you took away from that</p> <p>8 meeting is you must know the customers you're</p> <p>9 selling to first, right?</p> <p>10 A. Mm-hmm, yes.</p> <p>11 Q. And we looked at your document</p> <p>12 earlier today where you recounted it as you must</p> <p>13 also know your customers' customers, correct?</p> <p>14 A. Yes, to the best of your ability</p> <p>15 when you can.</p> <p>16 Q. The best of your ability, right?</p> <p>17 A. Yes.</p> <p>18 Q. What every reasonable</p> <p>19 manufacturer should do, right?</p> <p>20 MS. VANNI: Objection to form.</p> <p>21 THE WITNESS: If the information</p> <p>22 is available to you.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Right. And, certainly, if</p>	<p>1 Q. Okay. And something that you</p> <p>2 thought worthy of --</p> <p>3 A. Disagree.</p> <p>4 Q. You disagree?</p> <p>5 A. I disagree, yes.</p> <p>6 Q. Well, I mean, you'd agree that</p> <p>7 you made 33 billion pills of Vicodin, right?</p> <p>8 A. I would --</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: -- agree if I knew</p> <p>11 where those numbers came from.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. Well, you know, all I can do is</p> <p>14 work with what your former employer gives me,</p> <p>15 and that's what they've told us it is.</p> <p>16 MS. VANNI: Object to colloquy.</p> <p>17 MR. BUCHANAN: Let's move forward</p> <p>18 to exhibit internal number 588. You can</p> <p>19 set that one aside, ma'am.</p> <p>20 (Document marked for</p> <p>21 identification as Par-Norton Deposition</p> <p>22 Exhibit No. 14.)</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Passing you next in order is</p>

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<p style="text-align: right;">Page 334</p> <p>1 Exhibit Number 14. There you go. Copy for 2 counsel, please. 3 Next in order, ma'am, is a SOMS 4 update. Do you see you scheduling a conference 5 call to update folks? 6 A. Yes. 7 Q. We don't have the -- 8 A. Not sure who, yeah. 9 Q. I was just going to say, we don't 10 know who the invitees are. This is just the way 11 we get them. They're already printed out and 12 stamped when we get them, for the most part. 13 Some of these come to us natively, but you will 14 see that on the next page. 15 This is from November of 2013. 16 MR. BUCHANAN: What did we call 17 this, 14? Exhibit 14. Can we put it up 18 on the screen? Bradley, let's go to the 19 third -- fourth page. 20 BY MR. BUCHANAN: 21 Q. "SOMS Program Update, November 7, 22 2013." This is a presentation you pulled 23 together for a teleconference or a meeting? 24 A. Yes, looks that way.</p>	<p style="text-align: right;">Page 336</p> <p>1 And so we know, ma'am, that you 2 had received a letter by 2007 -- and I guess you 3 weren't at Qualitest then, but you were at 4 Watson or Anda, where manufacturers and 5 distributors received a letter concerning 6 maintenance of effective controls against 7 diversion. 8 Do you recall that? 9 A. Yes. 10 MS. KOSKI: Object to form. 11 MS. LEIBELL: Object to form. 12 BY MR. BUCHANAN: 13 Q. And the obligation -- the 14 obligation that manufacturers and distributors 15 had to maintain effective controls against 16 diversion, right? 17 A. Yes. 18 Q. Okay. And what this is saying as 19 of the fall of 2013 is that Phase I of this 20 revamp is to implement a basic SOMS program for 21 all of your customers, right; that's one part, 22 correct? 23 MS. VANNI: Object to form. 24 THE WITNESS: That's what it</p>
<p style="text-align: right;">Page 335</p> <p>1 Q. Okay. And you broke down what 2 was happening with regard to the SOMS program 3 into multiple phases, right? 4 A. Yes. 5 Q. You had steps that you were going 6 to implement as you tried to revamp things, 7 right? 8 MS. VANNI: Object to form. 9 THE WITNESS: Yes. 10 BY MR. BUCHANAN: 11 Q. Okay. Phase I, your first step 12 was to implement a basic SOMS program, right? 13 A. No. The first step was to 14 implement the basic SOMS program with 15 statistical algorithm, that's the rest of the 16 sentence there. 17 Q. Well, actually, it's not. If you 18 want to read the full sentence, I'm happy to. 19 It's "Implementation of a basic 20 SOMS program for all customers," right? 21 A. All controlled substances and 22 pseudoephedrine products based on statistical 23 algorithm. 24 Q. Right.</p>	<p style="text-align: right;">Page 337</p> <p>1 says. 2 BY MR. BUCHANAN: 3 Q. For all controlled substances, 4 correct? 5 A. That's what it says, yes. 6 Q. With a statistical algorithm? 7 A. Yes, that's correct. 8 Q. Okay. And so one of the things 9 you were doing then to implement this for all 10 classes of trade and all customers and for all 11 controlled substances in the fall of 2013 is you 12 hired this company, Cegedim -- am I pronouncing 13 that right? 14 A. Yes. 15 Q. Is it Cegedim? 16 A. Cegedim. 17 Q. Cegedim, okay. You hired Cegedim 18 to help you put together an algorithm that would 19 do what's reflected here, right? 20 A. Yes. 21 Q. And to implement it not just for 22 some customers, but to implement it for all 23 classes of trade and all customers, right? 24 MS. VANNI: Object to form.</p>

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<p style="text-align: right;">Page 338</p> <p>1 THE WITNESS: Basically to</p> <p>2 automate the program, yes.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. Phase II is to "Hire individuals</p> <p>5 to support the program," right?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Well, let's go back, I'm</p> <p>8 sorry, to Phase I. You said to automate the</p> <p>9 program.</p> <p>10 We've looked at documents today,</p> <p>11 you agree we've looked at documents where the</p> <p>12 company is saying it was only looking at retail</p> <p>13 pharmacies as a class of trade.</p> <p>14 Do you recall looking at those</p> <p>15 documents, ma'am, yes or no?</p> <p>16 A. Yes, we were only looking at</p> <p>17 retail customers for the SOMS program, not the</p> <p>18 OMS program.</p> <p>19 Q. Thank you.</p> <p>20 "Phase II, Hire individuals to</p> <p>21 support the program," right? 588.6, that's on</p> <p>22 the screen to your -- we put one to your left</p> <p>23 too. That may not be the most optimal location.</p> <p>24 A. Yes, I see it. This is good.</p>	<p style="text-align: right;">Page 340</p> <p>1 Q. Was there a manager of the SOM</p> <p>2 program in title, prior to that point in time?</p> <p>3 A. Not that title, no.</p> <p>4 Q. Right.</p> <p>5 There was no manager of the SOM</p> <p>6 program in Qualitest prior to September of</p> <p>7 2014 -- 2013, excuse me?</p> <p>8 A. Yes, that's correct. Doesn't</p> <p>9 mean it wasn't being done.</p> <p>10 Q. All right. So -- and someone</p> <p>11 else is going to decide that, ma'am, so let's --</p> <p>12 can we agree there was nobody at Qualitest who</p> <p>13 had that title prior to September of 2013?</p> <p>14 A. Not that title, correct.</p> <p>15 Q. Okay. And what you noted here is</p> <p>16 you're going to hire individuals to support the</p> <p>17 program, right?</p> <p>18 A. Yes.</p> <p>19 Q. One of the things you did was you</p> <p>20 hired somebody as director of SOMS,</p> <p>21 Mr. Brantley?</p> <p>22 A. Manager of SOMS, yes.</p> <p>23 Q. There you go.</p> <p>24 "All individuals on board and</p>
<p style="text-align: right;">Page 339</p> <p>1 Q. Okay. So, certainly, if you're</p> <p>2 going to have an effective program, you've got</p> <p>3 to have people as part of this process, right?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 THE WITNESS: We had people as</p> <p>6 part of the process. They were just in</p> <p>7 sales and the perception was not good,</p> <p>8 so we moved them into compliance.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Right.</p> <p>11 And you're going to have to put</p> <p>12 boots on the ground too and do due diligence</p> <p>13 visits and do all kinds of stuff, right?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: So that sales</p> <p>16 doesn't have to do it, yes.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Well, one of things we know you</p> <p>19 did is you brought in Mr. Brantley, right?</p> <p>20 A. Yes, I did.</p> <p>21 Q. I mean, you needed -- I mean,</p> <p>22 what was his title?</p> <p>23 A. He was a manager of the SOM</p> <p>24 program.</p>	<p style="text-align: right;">Page 341</p> <p>1 actively working on other aspects of the</p> <p>2 program," right?</p> <p>3 A. Yes.</p> <p>4 Q. One of things you needed was</p> <p>5 personnel training, right?</p> <p>6 A. Yes.</p> <p>7 Q. You had to implement SOPs, right?</p> <p>8 A. Yes.</p> <p>9 Q. You had to develop</p> <p>10 questionnaires, distribute questionnaires, get</p> <p>11 responses from questionnaires for their customer</p> <p>12 SOMS data, right?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. You had to create customer</p> <p>15 boundaries, that was one of the things you were</p> <p>16 going to do, right?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 THE WITNESS: That was using the</p> <p>19 IMS data.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Okay. So to create as part of</p> <p>22 this individual customer boundary so that you'd</p> <p>23 have flags as to unusual order sizes when they</p> <p>24 went beyond boundaries for various classes of</p>

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<p style="text-align: right;">Page 342</p> <p>1 trade, right?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: Yes, for the</p> <p>4 automated system, yes.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. And the next thing here that you</p> <p>7 were going to implement is due diligence visits,</p> <p>8 right?</p> <p>9 A. Yes, by someone with compliance.</p> <p>10 Q. And it sounds, ma'am, like what's</p> <p>11 happening is -- withdrawn.</p> <p>12 Phase III, next page. 588.7.</p> <p>13 A. Yes.</p> <p>14 Q. "Develop capability to easily</p> <p>15 access, trend and sort chargeback data,"</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. You worked with the vendor from</p> <p>19 IQ2020, or you worked with a vendor called</p> <p>20 IQ2020.</p> <p>21 Do you recall that?</p> <p>22 A. We gave a demo. I had seen a</p> <p>23 demo from them previously, and we shared that</p> <p>24 demo with the finance folks.</p>	<p style="text-align: right;">Page 344</p> <p>1 Q. All right. And we've talked</p> <p>2 about what the old program was, and this talked</p> <p>3 about what it covered, and now we're talking</p> <p>4 about your various phases for revamping it,</p> <p>5 right?</p> <p>6 A. Yes, the enhancements to the</p> <p>7 existing program.</p> <p>8 Q. Okay. Next, Phase IV, boots on</p> <p>9 the ground, right?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. "Customer Due Diligence</p> <p>12 Visits," right, know your customer?</p> <p>13 A. Yes, correct.</p> <p>14 Q. Okay. Because there were some</p> <p>15 direct customers that were in the DEA binder,</p> <p>16 you know, some big distributors, right?</p> <p>17 A. Yes.</p> <p>18 Q. There were six, I think, charts</p> <p>19 that reflected McKesson. There were five that</p> <p>20 reflected CVS. There were two that reflected HD</p> <p>21 Smith, right?</p> <p>22 A. Our intent was to target the</p> <p>23 customers that were identified in there first,</p> <p>24 yes.</p>
<p style="text-align: right;">Page 343</p> <p>1 Q. Okay. And so a demo was given to</p> <p>2 the finance folks. You said an agreement was</p> <p>3 reached with them, right?</p> <p>4 A. Yes.</p> <p>5 Q. IT resources were implemented to</p> <p>6 capture the feed, right?</p> <p>7 MS. VANNI: Object to form.</p> <p>8 THE WITNESS: Yes.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. And then you're going to plan to</p> <p>11 further develop this with leadership, I guess</p> <p>12 that's Mike and Trey?</p> <p>13 A. That's the sales team.</p> <p>14 Q. Got you.</p> <p>15 That was Phase III, right, and</p> <p>16 that's chargeback data?</p> <p>17 A. Yes.</p> <p>18 Q. That was another new addition to</p> <p>19 the program, right?</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: That was one new</p> <p>22 addition to the program, one improvement</p> <p>23 to the existing program, yes.</p> <p>24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 345</p> <p>1 Q. Right. And these have been</p> <p>2 called out in the DEA binder as, hey, these are</p> <p>3 people that you're buying they're well above the</p> <p>4 norms, right?</p> <p>5 MS. VANNI: Object to form.</p> <p>6 THE WITNESS: They had large</p> <p>7 quantities that needed to be researched</p> <p>8 or DEA thought they were large</p> <p>9 quantities, yes.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Right. So you were going to put</p> <p>12 boots on the ground first to customers that had</p> <p>13 been flagged, right?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. In that DEA presentation, right?</p> <p>17 A. Yes.</p> <p>18 Q. But you also sent out a dear</p> <p>19 valued customer to every customer, correct?</p> <p>20 A. Correct.</p> <p>21 Q. That was the October 18 letter</p> <p>22 that we looked at earlier today, correct?</p> <p>23 A. The October, yes, 2013.</p> <p>24 Q. I meant October 18, 2013 letter,</p>

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<p style="text-align: right;">Page 346</p> <p>1 thank you.</p> <p>2 A. Yes.</p> <p>3 Q. And you sent a notice to your</p> <p>4 direct customers that there were customers of</p> <p>5 their customers -- customers of that customer</p> <p>6 that had been flagged as part of that DEA</p> <p>7 presentation, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Okay.</p> <p>10 A. We couldn't contact them</p> <p>11 directly, so we went through the direct</p> <p>12 customer.</p> <p>13 Q. Okay. "SOMS Brand Business</p> <p>14 Analysis," is it correct, ma'am, that you did</p> <p>15 not have responsibility in your DEA compliance</p> <p>16 role for what was happening on the branded side,</p> <p>17 and we'll just call that Endo?</p> <p>18 A. Yes, that's correct.</p> <p>19 Q. Okay. Now, before the DEA told</p> <p>20 you that your current SOMS system was</p> <p>21 inadequate, you had been told that by other</p> <p>22 people, right?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 THE WITNESS: DEA actually didn't</p>	<p style="text-align: right;">Page 348</p> <p>1 THE WITNESS: Yes, I believe so.</p> <p>2 MR. BUCHANAN: Okay. Could we</p> <p>3 pull it up on the screen.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. This is an e-mail from yourself</p> <p>6 to Ms. Connell. She was -- was she your boss?</p> <p>7 A. She was my boss at the time.</p> <p>8 Q. Okay. "Subject: DEA Compliance</p> <p>9 Initiatives Presentation," and there's a</p> <p>10 PowerPoint that's attached entitled "DEA</p> <p>11 Compliance Initiative" from February 9, 2013.</p> <p>12 Do you see that, ma'am?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. At 1052.3 there's a</p> <p>15 summary of this particular meeting with Buzzeo</p> <p>16 PDMA.</p> <p>17 Do you see that at the top?</p> <p>18 A. Yes.</p> <p>19 Q. "On January 16th and 17th, 2013,</p> <p>20 a review of our Suspicious Order Monitoring</p> <p>21 System was conducted by external consultants</p> <p>22 working for Buzzeo PDMA."</p> <p>23 Do you see that?</p> <p>24 A. Yes, I do.</p>
<p style="text-align: right;">Page 347</p> <p>1 tell us it was inadequate.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Well, we have the -- we have the</p> <p>4 discussion --</p> <p>5 A. We have the discuss --</p> <p>6 Q. -- and the jury can characterize</p> <p>7 those findings, and we have your words on it as</p> <p>8 well from that time, but let's -- before that</p> <p>9 meeting in March, you had had interactions with</p> <p>10 the company -- with consultants concerning your</p> <p>11 SOMS system, correct?</p> <p>12 A. I don't recall who.</p> <p>13 Q. Okay. Let's start with --</p> <p>14 MR. BUCHANAN: Can I have 1052.</p> <p>15 (Document marked for</p> <p>16 identification as Par-Norton Deposition</p> <p>17 Exhibit No. 15.)</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Passing you, ma'am, what we're a</p> <p>20 marking as Exhibit 15 to your deposition.</p> <p>21 You had some of these folks from</p> <p>22 Cegedim and Buzzeo come in and to look at your</p> <p>23 system in 2013, right?</p> <p>24 MS. VANNI: Object to form.</p>	<p style="text-align: right;">Page 349</p> <p>1 Q. Okay. The paragraph in the</p> <p>2 middle begins, "The consultants concluded."</p> <p>3 Do you see that?</p> <p>4 A. I do.</p> <p>5 Q. Can you read that into the</p> <p>6 record, ma'am?</p> <p>7 A. "The consultants concluded that</p> <p>8 our current SOM program, systems and procedures</p> <p>9 do not meet the regulatory requirements."</p> <p>10 Q. Let's pause there.</p> <p>11 A. Mm-hmm.</p> <p>12 Q. This is -- of course, just to</p> <p>13 orient ourselves in time, this is two months</p> <p>14 prior to sitting down with the DEA, correct?</p> <p>15 A. Correct.</p> <p>16 Q. And what your consultants told</p> <p>17 you as of this point in time and before the time</p> <p>18 with the DEA is that your current SOM program,</p> <p>19 systems and procedures do not even meet the</p> <p>20 regulatory requirements, right?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: Right, because if</p> <p>23 they met the regulatory requirements,</p> <p>24 they wouldn't be able to charge us large</p>

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<p style="text-align: right;">Page 350</p> <p>1 sums to implement a new program.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Well, certainly, ma'am, before</p> <p>4 somebody had to sit in this chair and talk about</p> <p>5 this document --</p> <p>6 A. Whether somebody sat in this</p> <p>7 chair or not.</p> <p>8 Q. Well, you certainly didn't write</p> <p>9 that, right?</p> <p>10 MS. VANNI: Object to form.</p> <p>11 THE WITNESS: We wrote what this</p> <p>12 is. It's minutes.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. I invite you to review this and</p> <p>15 say -- and see if at any point in time you wrote</p> <p>16 here, we have to take this all with a grain of</p> <p>17 salt because they're just trying to make money?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. In words or substance?</p> <p>21 A. I actually didn't write this.</p> <p>22 Q. Okay. Can we see in there</p> <p>23 anywhere where the author of this characterized</p> <p>24 in words or substance they're just trying to</p>	<p style="text-align: right;">Page 352</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And so the consultants</p> <p>3 concluded that your current systems, procedures</p> <p>4 and program for SOM did not meet the regulatory</p> <p>5 requirements, and then they made specific</p> <p>6 recommendations, correct?</p> <p>7 A. Yes, that's what it says.</p> <p>8 Q. Okay. And one of the</p> <p>9 recommendations they made was increase the</p> <p>10 amount of initial due diligence to include on</p> <p>11 site meetings with customers to assure they have</p> <p>12 controls in place to safeguard against</p> <p>13 diversion.</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. That's what the DEA talked</p> <p>17 to you about two months later, right?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Okay. Let's go to item 2,</p> <p>22 "Remove the Sales &amp; Marketing and Customer</p> <p>23 Service functions from the SOM decision-making</p> <p>24 process as conducting this review is contrary to</p>
<p style="text-align: right;">Page 351</p> <p>1 make money off us?</p> <p>2 MS. VANNI: Object to the form.</p> <p>3 THE WITNESS: They wouldn't put</p> <p>4 that in here because they're trying --</p> <p>5 we're trying to bring this company on to</p> <p>6 make improvements to the system.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. Right.</p> <p>9 So what they wrote is the</p> <p>10 consultants concluded that our current -- and</p> <p>11 they spent two days with you, right?</p> <p>12 A. I'm not sure. It says, "Tracey</p> <p>13 was not able to participate due to an</p> <p>14 unannounced DEA inspection."</p> <p>15 Q. Right.</p> <p>16 So we have Aimee Cooper, Bambi</p> <p>17 McGaha, Ricky Richardson, Larry Shaffer and</p> <p>18 Jeremy Tatum, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And we talked about Mr. -- I</p> <p>21 pronounced it Shaffer again.</p> <p>22 A. Shaffer.</p> <p>23 Q. Mr. Shaffer was in your</p> <p>24 organization?</p>	<p style="text-align: right;">Page 353</p> <p>1 their primary mission of helping accounts with</p> <p>2 their current business and encouraging new</p> <p>3 business," right?</p> <p>4 A. That's what the minutes say, yes.</p> <p>5 Q. Right. And, in fact, I mean, you</p> <p>6 heard the same thing from the DEA in March,</p> <p>7 right, that you got to take customer service and</p> <p>8 sales out of the site inspection and out of that</p> <p>9 process, correct?</p> <p>10 A. Yes.</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: The perception is</p> <p>13 there.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Well, in fact, these consultants,</p> <p>16 not just the DEA, these consultants who you</p> <p>17 called in to do an inspection of your system,</p> <p>18 told you that you got to get customer service</p> <p>19 and sales and marketing out of the SOM process,</p> <p>20 right?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: Yes, they had that</p> <p>23 perception too.</p> <p>24 BY MR. BUCHANAN:</p>



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<p style="text-align: right;">Page 354</p> <p>1 Q. Okay. They raised a concern</p> <p>2 about your "Retail thresholds appear to be based</p> <p>3 upon perceived abuse potential and might be</p> <p>4 characterized as arbitrary."</p> <p>5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. And one of the things you did</p> <p>8 after the DEA presentation in March of 2013 was</p> <p>9 develop a different algorithm to develop your</p> <p>10 thresholds, correct?</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: We developed an</p> <p>13 algorithm to build pattern and frequency</p> <p>14 into the initial check.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Okay. So that your system, the</p> <p>17 system for suspicious order monitoring, I'm up</p> <p>18 to 5 on the next page, just trying to move</p> <p>19 quickly, ma'am, "System should be tested,</p> <p>20 validated and statistically defensible."</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Do you agree with that?</p> <p>24 A. Yes, that's their standard</p>	<p style="text-align: right;">Page 356</p> <p>1 A. That's correct.</p> <p>2 Q. Do you agree that --</p> <p>3 A. That's common sense.</p> <p>4 Q. Yeah, I mean, because if you</p> <p>5 share with customers what the thresholds are</p> <p>6 that you've set, they can structure their orders</p> <p>7 in a way so that they stay below the thresholds</p> <p>8 all the time but get to the same place in a</p> <p>9 different way?</p> <p>10 A. Right, which is why we didn't</p> <p>11 share those.</p> <p>12 Q. Right. So sharing thresholds,</p> <p>13 bad practice, right?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Working with orders to --</p> <p>16 working with customers to structure their orders</p> <p>17 so they stay within thresholds is not a good</p> <p>18 practice?</p> <p>19 A. No, it's not.</p> <p>20 MS. VANNI: Object to form.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. I mean, the manufacturer or the</p> <p>23 distributor should not be working with its</p> <p>24 primary customer to structure its order in a way</p>
<p style="text-align: right;">Page 355</p> <p>1 wording for that particular vendor, that's their</p> <p>2 standard wording, yes.</p> <p>3 Q. But do you agree, I mean, if</p> <p>4 you're going to have a system for detecting</p> <p>5 suspicious orders, that it should be tested,</p> <p>6 validated and defensible?</p> <p>7 A. Any computer system should be</p> <p>8 validated. It's an FDA requirement, yes.</p> <p>9 Q. Well, I'm not talking about FDA</p> <p>10 requirements, ma'am.</p> <p>11 I just want to know do you agree</p> <p>12 with regard to suspicious order monitoring, the</p> <p>13 system should be tested, validated and</p> <p>14 defensible?</p> <p>15 A. Yes.</p> <p>16 Q. Okay, good. Statistically</p> <p>17 defensible, you agree?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And they advised further</p> <p>20 that you should not provide customers for the</p> <p>21 reason their orders are held or pended as this</p> <p>22 may result in customers working to avoid the one</p> <p>23 item that caused the order to be declined.</p> <p>24 Do you see that?</p>	<p style="text-align: right;">Page 357</p> <p>1 to stay within whatever the red flag thresholds</p> <p>2 are, right?</p> <p>3 MS. VANNI: Object to form.</p> <p>4 THE WITNESS: No, that defeats</p> <p>5 the purpose of the program.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. Right.</p> <p>8 That's a very bad practice,</p> <p>9 right?</p> <p>10 A. Yes.</p> <p>11 Q. And if you're doing that kind of</p> <p>12 practice and you're certainly not maintaining</p> <p>13 effective controls against diversion, right?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: That's correct.</p> <p>16 However, customers can, over time, if</p> <p>17 they're a regular customer, kind of</p> <p>18 figure out what your threshold is. You</p> <p>19 don't communicate it to them, but if</p> <p>20 they're smart and they keep track of it,</p> <p>21 they can technically figure it out.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. But as a manufacturer, you need</p> <p>24 to be vigilant to make sure your customers are</p>

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<p style="text-align: right;">Page 358</p> <p>1 not structuring transactions to evade --</p> <p>2 A. Absolutely, yes.</p> <p>3 Q. -- these type of limits, correct?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 THE WITNESS: Yes.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. And then you go through to</p> <p>8 summarize in your PowerPoint, ma'am, and this is</p> <p>9 a PowerPoint that you obviously endorsed, right?</p> <p>10 MS. VANNI: Object to the form.</p> <p>11 THE WITNESS: I don't know if I</p> <p>12 created it.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. Well, if we go back to 1052.1.</p> <p>15 This is a PowerPoint you forwarded to your boss,</p> <p>16 right?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Ms. Connell was your boss</p> <p>19 at that point in time?</p> <p>20 A. Correct.</p> <p>21 Q. So, obviously, if you forwarded</p> <p>22 this, you, obviously, endorsed its content,</p> <p>23 right?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 360</p> <p>1 the consultant said.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Right. And so you certainly in</p> <p>4 passing along the information you received from</p> <p>5 the consultant, forwarded along their top level</p> <p>6 conclusion, right?</p> <p>7 MS. VANNI: Object to form.</p> <p>8 THE WITNESS: I was not at the</p> <p>9 meeting with the consultant, so I was</p> <p>10 just going by what the individual told</p> <p>11 me was said at the meeting and just</p> <p>12 communicating that information.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. And for the benefit of your</p> <p>15 boss --</p> <p>16 A. It does not --</p> <p>17 Q. -- in passing this along, top</p> <p>18 level conclusion that you passed along, "The</p> <p>19 consultants concluded that our current SOM</p> <p>20 program, systems and procedures do not meet the</p> <p>21 regulatory requirements," correct?</p> <p>22 A. That's what it says, yes.</p> <p>23 Q. And that was point one</p> <p>24 substantively that you conveyed to your boss,</p>
<p style="text-align: right;">Page 359</p> <p>1 MS. VANNI: Object to the form.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. And you forwarded along the</p> <p>4 Cegedim report and conclusions and</p> <p>5 recommendations, right?</p> <p>6 A. Yes, looks like I did.</p> <p>7 Q. And so the PowerPoint begins on</p> <p>8 -- I'm sorry, 1052.7.</p> <p>9 MR. BUCHANAN: If you can go</p> <p>10 there, please, Bradley, for everyone's</p> <p>11 benefit.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. And you've got your agenda on the</p> <p>14 next page and an overview of the Cegedim report,</p> <p>15 right?</p> <p>16 A. Yes.</p> <p>17 Q. And then you've got the first</p> <p>18 bullet on page 1052.10.</p> <p>19 A. Yes.</p> <p>20 Q. Called out for your boss, right?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. No qualifiers, right?</p> <p>23 MS. VANNI: Objection.</p> <p>24 THE WITNESS: Just repeating what</p>	<p style="text-align: right;">Page 361</p> <p>1 right?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: That doesn't mean I</p> <p>4 agreed with it, but yes.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Okay. Well, you certainly didn't</p> <p>7 put any qualifiers in what you sent to her,</p> <p>8 right?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: I wouldn't have put</p> <p>11 it in writing if I'm giving her what</p> <p>12 they said. We would have had a side</p> <p>13 conversation.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Okay. Specifically, they</p> <p>16 recommended we make the following changes,</p> <p>17 increase the amount of initial due diligence</p> <p>18 with customers, right?</p> <p>19 A. Yes.</p> <p>20 Q. To assure our customers have</p> <p>21 controls in place to safeguard against</p> <p>22 diversion, right?</p> <p>23 A. Yes, that's what it says.</p> <p>24 Q. To ensure or to assure our</p>

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<p style="text-align: right;">Page 362</p> <p>1 customers have their own robust SOMS program, 2 right? 3 A. Yes. 4 Q. So it's being recommended and 5 what you're communicating to your boss is having 6 due diligence that's going to confirm that your 7 customers have robust SOMS programs, right? 8 MS. VANNI: Object to form. 9 THE WITNESS: There's are all the 10 recommendations of the Cegedim report, 11 yes. 12 BY MR. BUCHANAN: 13 Q. Right. And this is months before 14 the DEA meeting, right? 15 A. Yes. 16 Q. Okay. Review their SOPs and 17 orders themselves, correct? 18 A. Yes. 19 Q. I mean, let me restate that. 20 "Increase the amount of initial 21 due diligence with customers to assure our 22 customers have their own robust SOMS program," 23 correct? 24 A. Yes, that's what it says.</p>	<p style="text-align: right;">Page 364</p> <p>1 meeting. 2 Q. Okay. "Remove the Sales &amp; 3 Marketing and Customer Service functions from 4 the SOM decision-making process," right? 5 A. Yes. 6 Q. Okay. And you note, "The DEA 7 Compliance Department is best suited for this 8 purpose as DEA compliance personnel have a 9 singular mission of protecting the firm from 10 regulatory issues and should be assigned the 11 primary role of conducting due diligence, 12 evaluating pending or possibly suspicious orders, 13 and clearing accounts or reporting the records 14 to DEA." 15 Did I read that correctly? 16 MS. VANNI: Object to form. 17 THE WITNESS: Quoted, yep, word 18 for word -- 19 BY MR. BUCHANAN: 20 Q. Makes perfect sense. 21 A. -- by the consultant, yes. 22 MS. VANNI: Object to form. 23 BY MR. BUCHANAN: 24 Q. Makes perfect sense?</p>
<p style="text-align: right;">Page 363</p> <p>1 Q. That's what you wrote. 2 "(Review of their SOPs and orders 3 they themselves have reported to DEA)," correct? 4 A. Yes. 5 Q. "Our process should include 6 on-site meetings (audits) for both Corporate 7 Offices and Distribution Centers," right? 8 A. That's what they said, yes. 9 Q. And that's what you communicated 10 to your boss, right? 11 MS. VANNI: Object to form. 12 THE WITNESS: Word for word what 13 the consultant reported. 14 BY MR. BUCHANAN: 15 Q. That's not quite word for word, 16 but you've recast it and put it in this form -- 17 A. Yes. 18 Q. -- for your boss, right? 19 MS. VANNI: Object to form. 20 BY MR. BUCHANAN: 21 Q. This is how you understood their 22 recommendation, correct? 23 A. This is what was told to me of 24 their recommendation. Again, I was not at that</p>	<p style="text-align: right;">Page 365</p> <p>1 A. These are their opinions, yes. 2 Q. Okay. Well, I mean, look you 3 pay -- you brought them in, right? 4 A. Yes, they have -- 5 Q. You brought them in for the 6 experience they could bring to the evaluation to 7 evaluate your system and give you 8 recommendations, right? 9 A. I brought them in for their 10 electronic monitoring system, which was the best 11 in the industry at the time. 12 Q. You brought them in to conduct an 13 audit of your suspicious order monitoring 14 system, correct? 15 MS. VANNI: Object to form. 16 THE WITNESS: I didn't need them 17 to conduct an audit. I'm capable of 18 conducting an audit myself. 19 BY MR. BUCHANAN: 20 Q. Okay. So you're saying this was 21 all known to you then as of this point in time, 22 correct? 23 MS. VANNI: Object to form. 24 THE WITNESS: I did not agree --</p>

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<p style="text-align: right;">Page 366</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. You were aware of all these</p> <p>3 points?</p> <p>4 A. I did not agree with their</p> <p>5 recommendations. I knew the condition of our</p> <p>6 current SOM program, and I knew I wanted to make</p> <p>7 improvements.</p> <p>8 Q. The further recommendation is</p> <p>9 "Discontinue the use of thresholds and forecasts</p> <p>10 as part of the SOMS model," correct?</p> <p>11 A. That's what the recommendation</p> <p>12 was, yes.</p> <p>13 Q. Telling you that "All customers</p> <p>14 orders must be evaluated in real time against</p> <p>15 quantity, frequency and pattern and compared to</p> <p>16 orders of others in the same class of trade,"</p> <p>17 right?</p> <p>18 A. Yes.</p> <p>19 Q. And then it goes through other</p> <p>20 details, some of which we've discussed, right?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. And you're saying this is one of</p>	<p style="text-align: right;">Page 368</p> <p>1 you that, that was, in fact, the consultants you</p> <p>2 hired and paid good money to come in and assess</p> <p>3 your system?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 THE WITNESS: The consultants</p> <p>6 that got it from DEA, yes.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. Okay. The "System should be</p> <p>9 tested validated and statistically defensible,"</p> <p>10 right?</p> <p>11 A. Yes.</p> <p>12 Q. And, again, you echoed upstream</p> <p>13 that should not be telling your customers the</p> <p>14 reason their orders are pended, right?</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. And so you then come forward with</p> <p>19 a phased implementation process around these</p> <p>20 very recommendations, right?</p> <p>21 A. Similar, yes.</p> <p>22 Q. Well, DCT is you, right?</p> <p>23 A. Yes.</p> <p>24 Q. That's your group?</p>
<p style="text-align: right;">Page 367</p> <p>1 the things you were looking for from them,</p> <p>2 right? They had a system that would do this and</p> <p>3 you wanted to implement that system?</p> <p>4 A. The electronic system that would</p> <p>5 tie into our order system, yes.</p> <p>6 Q. Okay. They further recommended</p> <p>7 to evaluate orders based on active ingredient</p> <p>8 quantity rather than by dose count, right?</p> <p>9 A. Yes.</p> <p>10 Q. They recommended to you to</p> <p>11 utilize chargeback data, right?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: Where are you</p> <p>14 seeing that?</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. I'm on 1052.12. Evaluate orders</p> <p>17 based on active ingredient quantity rather than</p> <p>18 by dose count within a specific product family.</p> <p>19 The second bullet says, "Utilize chargeback data</p> <p>20 to evaluate downstream distribution of our</p> <p>21 products."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. So that wasn't just DEA telling</p>	<p style="text-align: right;">Page 369</p> <p>1 A. Drug compliance group, yes.</p> <p>2 Q. And this is your PowerPoint,</p> <p>3 right?</p> <p>4 A. It is, mm-hmm.</p> <p>5 Q. Sent upstream to your boss,</p> <p>6 right?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. First, let's talk about</p> <p>9 Phase I. Obviously, you're going to bring in</p> <p>10 somebody that's going to help strengthen your</p> <p>11 system of evaluating orders, right?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: To implement the</p> <p>14 electronic system, yes.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Cegedim, right?</p> <p>17 A. Yes.</p> <p>18 Q. You're going to bring them in,</p> <p>19 right?</p> <p>20 A. Correct.</p> <p>21 Q. Okay. Two, you're going to</p> <p>22 update the SOMS SOP to reflect the new process?</p> <p>23 A. Right.</p> <p>24 Q. You're going to review and lay</p>

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<p style="text-align: right;">Page 370</p> <p>1 out plans to integrate system requirements</p> <p>2 between the order system and the Cegedim system</p> <p>3 for order monitoring, right?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. Further, in this phased</p> <p>6 approach, Phase II, you're going to look at all</p> <p>7 products, not just some products, right?</p> <p>8 A. We were adding the chemicals</p> <p>9 which are not required to be regulated to be</p> <p>10 handled in that way by DEA, but we were adding</p> <p>11 them.</p> <p>12 Q. You're going to start doing</p> <p>13 search trending, right?</p> <p>14 A. Search --</p> <p>15 Q. Sales trending?</p> <p>16 A. Sales trending.</p> <p>17 Q. Yes.</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. You're going to start doing sales</p> <p>22 trending to assist with discovery of customer</p> <p>23 ordering patterns, frequencies and sizes, right?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 372</p> <p>1 A. Right.</p> <p>2 MS. VANNI: Form.</p> <p>3 THE WITNESS: Things that were</p> <p>4 not happening by the compliance team or</p> <p>5 things that I wanted to improve.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. Right.</p> <p>8 Well, certainly, here it doesn't</p> <p>9 note that our sales force is doing on-site</p> <p>10 customer evaluations for compliance, right?</p> <p>11 A. Didn't need to be. It was an</p> <p>12 internal document, and that was well known.</p> <p>13 Q. And next you proposed as Phase</p> <p>14 III accessing chargeback data, correct, ma'am?</p> <p>15 A. Yes.</p> <p>16 Q. Before the DEA ever even told</p> <p>17 you, right?</p> <p>18 A. Correct. It was brought up at</p> <p>19 other conferences.</p> <p>20 Q. Right. So you didn't need this</p> <p>21 meeting with the DEA in March to know that,</p> <p>22 right?</p> <p>23 A. Well, I know that other</p> <p>24 manufacturers --</p>
<p style="text-align: right;">Page 371</p> <p>1 Q. Including geographical</p> <p>2 distributions. These are your recommendations</p> <p>3 before the DEA ever sat down with you, right?</p> <p>4 A. Right, the geographical, mm-hmm,</p> <p>5 yes.</p> <p>6 Q. As somebody in the industry with</p> <p>7 experience in SOMS and also anti-diversion</p> <p>8 efforts, right?</p> <p>9 A. And sitting at DEA conferences,</p> <p>10 yes.</p> <p>11 Q. Okay. And Phase III, you're</p> <p>12 going to start doing on-site customer</p> <p>13 evaluations, right?</p> <p>14 A. Yes.</p> <p>15 Q. That was before you met with the</p> <p>16 DEA, right?</p> <p>17 A. Those were things we were --</p> <p>18 Q. On-site customer evaluations?</p> <p>19 A. Things we were moving towards,</p> <p>20 yes.</p> <p>21 Q. 1052.15, right?</p> <p>22 A. Yes.</p> <p>23 Q. And things that were not</p> <p>24 happening before?</p>	<p style="text-align: right;">Page 373</p> <p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: -- were using</p> <p>3 chargeback data, and it was something</p> <p>4 that I was looking into.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Right. So one of the things you</p> <p>7 were going to do is you're going to start</p> <p>8 accessing chargeback data and also third party</p> <p>9 data sources, right?</p> <p>10 A. IMS, yes.</p> <p>11 Q. IMS, right.</p> <p>12 This provides visibility of</p> <p>13 product flow down the customer stream and allows</p> <p>14 for enhanced compliance for the "Know Your</p> <p>15 Customer" requirement of the DEA, correct?</p> <p>16 A. I thought it would, yes.</p> <p>17 Q. Right.</p> <p>18 And so as of 2013, before you</p> <p>19 ever met with the DEA, you were aware of the</p> <p>20 know your customer obligation, correct?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. You were aware of the</p>

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<p style="text-align: right;">Page 374</p> <p>1 availability of chargeback data because you were 2 going to start to access it, right? 3 MS. VANNI: Object to form. 4 THE WITNESS: We were looking 5 into it to see if it really provided 6 what DEA thought it did. 7 BY MR. BUCHANAN: 8 Q. And what you wrote here was Phase 9 III was to access chargeback data and third 10 party data, right? 11 A. Yes. 12 Q. And we can agree this is two 13 months before you melt with the FDA -- excuse 14 me -- DEA? 15 A. Yes. 16 Q. Thank you. You can set that 17 aside. 18 (Document marked for 19 identification as Par-Norton Deposition 20 Exhibit No. 16.) 21 BY MR. BUCHANAN: 22 Q. Passing you, ma'am, what we're 23 marking as 1071 to your deposition -- I'm sorry. 24 That's false. I'm passing you what we're</p>	<p style="text-align: right;">Page 376</p> <p>1 If we can go to 1071.5. We have 2 the same graphic off to the right. 3 Do you see that? 4 A. I do. 5 Q. Where you've got the Quota Grant 6 Process, the Manufacturing Site Compliance, Data 7 Integrity and Suspicious Order Monitoring as 8 critical elements of DEA compliance? 9 A. Correct. 10 Q. Correct? Suspicious order 11 monitoring we talked about that and your phrase 12 here mirrors the one in the other document, 13 correct? 14 A. Yes. 15 Q. Implement a solution and 16 implement a solution, correct? 17 A. Implement a solution is what it 18 says, you must implement one. 19 Q. "Implement a solution that 20 proactively discloses suspicious orders based on 21 unusual size, order pattern, deviation and 22 unusual frequency," correct? 23 A. Yes. 24 Q. Okay.</p>
<p style="text-align: right;">Page 375</p> <p>1 marking as Exhibit 16. I've got a separate 2 number on mine. 3 MR. BUCHANAN: Could we pull up 4 1071 on the screen. 5 This is an e-mail exchange -- 6 excuse me. What exhibit did I pass you, 7 on the top right corner, is it 1052? 8 MS. VANNI: No, 1071.1. 9 MR. BUCHANAN: Okay. It should 10 be 1071. Are we on the same page? We 11 are, good. 12 THE WITNESS: 1071. 13 BY MR. BUCHANAN: 14 Q. Okay. This is Exhibit 16 to your 15 deposition. It's an e-mail exchange between 16 yourself and Ms. Connell again, DEA Compliance 17 Initiative Presentation. This is from 2/9, and 18 the attachment is "DEA Compliance Improvement 19 Initiative." 20 Do you see that? 21 A. Yes. 22 Q. Contents are on page 1071.3. 23 Executive summary, SWOT analysis, DEA compliance 24 team and then action summaries and other things.</p>	<p style="text-align: right;">Page 377</p> <p>1 A. This is not talking about the 2 current state of the business. It's talking 3 about the requirements for DEA. 4 Q. Let's go to 1071.8. 5 There's an analysis of current 6 weaknesses, right? 7 A. Yes. 8 Q. Okay. Weaknesses and there's 9 strengths and opportunities and threats and all 10 kinds of things. I'm not going to have time to 11 go through all of this with you. 12 One of the weaknesses at this 13 point in time was you had a lack of resources, 14 right? 15 A. Yes. 16 Q. Limited talent pool and limited 17 investments in the group, right? 18 MS. VANNI: Object to form. 19 THE WITNESS: I'm not sure what 20 the investments means, to be honest, but 21 the talent pool, yes. 22 BY MR. BUCHANAN: 23 Q. Another weakness you had was a 24 "lack of training &amp; compliance first culture,"</p>

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<p style="text-align: right;">Page 378</p> <p>1 right?</p> <p>2 A. Yes.</p> <p>3 Q. Compliance first culture meaning</p> <p>4 we got to do this, it's really important that we</p> <p>5 do it, right?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: I'm again not sure</p> <p>8 what first culture means. Some of those</p> <p>9 words, I have a feeling Sanjay</p> <p>10 participated in this.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Okay. And what's the next</p> <p>13 weakness?</p> <p>14 A. "Inadequate SOMS."</p> <p>15 We wanted it to be stronger.</p> <p>16 Q. Let's be clear, the words you</p> <p>17 wrote were "inadequate SOMS," correct, ma'am?</p> <p>18 A. Correct. Current program is not</p> <p>19 adequate for my standards.</p> <p>20 Q. Okay. And what we're looking at</p> <p>21 here is could you remind us, ma'am, is this</p> <p>22 before or after you sat down with the DEA?</p> <p>23 A. This is before.</p> <p>24 Q. Okay. So even before you sat</p>	<p style="text-align: right;">Page 380</p> <p>1 Q. Well, we can agree it doesn't say</p> <p>2 that?</p> <p>3 A. We can agree you can interpret it</p> <p>4 however you would like, but that's not what it</p> <p>5 meant.</p> <p>6 Q. What you wrote was "inadequate</p> <p>7 SOMS," correct?</p> <p>8 A. That's what's stated there,</p> <p>9 correct.</p> <p>10 Q. Okay. And SOMS are suspicious</p> <p>11 order monitoring systems?</p> <p>12 A. Yes. Inadequate means you have</p> <p>13 one, you just want to improve it.</p> <p>14 Q. Okay. So --</p> <p>15 A. It doesn't say nonexistent.</p> <p>16 Q. Inadequate means not adequate,</p> <p>17 right?</p> <p>18 A. Not adequate by whose standards?</p> <p>19 By mine in this case.</p> <p>20 Q. Not adequate, correct?</p> <p>21 A. By my standards, yes.</p> <p>22 Q. That's what -- you were the head</p> <p>23 of DEA compliance as of this point in time,</p> <p>24 correct?</p>
<p style="text-align: right;">Page 379</p> <p>1 down with the DEA and spent the three hours in</p> <p>2 DC with them, I mean, you knew you had</p> <p>3 inadequate SOMS, right?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 THE WITNESS: I knew I had</p> <p>6 improvements that I wanted to make.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. I understand that's how it's</p> <p>9 characterized here in the record, ma'am, but</p> <p>10 what you wrote to your boss is we have</p> <p>11 inadequate SOMS correct?</p> <p>12 MS. VANNI: Objection.</p> <p>13 THE WITNESS: That's what the</p> <p>14 document says versus what is --</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. And that's what you put into it?</p> <p>17 A. Yeah.</p> <p>18 Q. Okay. And what you forwarded up</p> <p>19 the food chain in Qualitest at that point in</p> <p>20 time, correct?</p> <p>21 MS. VANNI: Objection.</p> <p>22 THE WITNESS: Correct, because</p> <p>23 improvements we wanted to make.</p> <p>24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 381</p> <p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: And I had very high</p> <p>3 goals and standards.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. And we can agree not only your</p> <p>6 standards that was inadequate by but inadequate</p> <p>7 by the consultants who you met with, correct?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: Because they wanted</p> <p>10 the business, yes.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Okay. We can agree before the</p> <p>13 DEA told you that your SOMS system was</p> <p>14 inadequate, you had concluded it was inadequate,</p> <p>15 correct?</p> <p>16 MS. VANNI: Object to form.</p> <p>17 THE WITNESS: DEA did not say the</p> <p>18 SOMS system was inadequate. If they</p> <p>19 found it to be inadequate, we would have</p> <p>20 gotten violations. We did not get</p> <p>21 violations for our SOM system.</p> <p>22 MR. BUCHANAN: Move to strike.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Okay. We have the DEA statements</p>

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<p style="text-align: right;">Page 382</p> <p>1 with regard to your system.</p> <p>2 A. You have them.</p> <p>3 Q. And we have your statements with</p> <p>4 regard to the SOM system before you sat with the</p> <p>5 DEA, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And you noted you had an</p> <p>8 inadequate SOM system, correct?</p> <p>9 THE WITNESS: That's what's</p> <p>10 written.</p> <p>11 MS. VANNI: Object to form.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. We know that you met with -- you</p> <p>14 had consultants that came and then looked at</p> <p>15 your system in 2013, right?</p> <p>16 A. Yes.</p> <p>17 Q. Before you met with the DEA</p> <p>18 right?</p> <p>19 A. Yes.</p> <p>20 Q. And they said it was inadequate,</p> <p>21 correct?</p> <p>22 A. Inadequate by -- yes.</p> <p>23 Q. Okay. Let's go forward to</p> <p>24 1071.20. And, regrettably, I'm not going to</p>	<p style="text-align: right;">Page 384</p> <p>1 THE WITNESS: That was the goal,</p> <p>2 yes.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. Okay. One of your other Phase</p> <p>5 III items was to implement, those were the words</p> <p>6 you used, right, implement?</p> <p>7 You see that?</p> <p>8 A. Yes.</p> <p>9 Q. On-site customer audits, correct?</p> <p>10 A. Correct.</p> <p>11 Q. Utilizing an external audit team,</p> <p>12 correct?</p> <p>13 A. That's what it says, yes, by</p> <p>14 compliance.</p> <p>15 Q. You can set that aside.</p> <p>16 MR. BUCHANAN: Do you mind if we</p> <p>17 take an earlier break? How many minutes</p> <p>18 are we? Can we just take a break. I</p> <p>19 just need to shuffle some papers so I</p> <p>20 provide appropriate time for my</p> <p>21 co-counsel.</p> <p>22 MS. VANNI: That's fine.</p> <p>23 THE VIDEOGRAPHER: Off the record</p> <p>24 now, it's 3:15 p m. Off the record.</p>
<p style="text-align: right;">Page 383</p> <p>1 have time to go through all of this with you,</p> <p>2 but I'd like to focus on action area suspicious</p> <p>3 order monitoring system.</p> <p>4 Again, we see phases of the</p> <p>5 "Proposed Next Steps," correct?</p> <p>6 A. Correct.</p> <p>7 Q. The purpose to implement a robust</p> <p>8 system to guarantee reliability and legit -- in</p> <p>9 the legitimacy of our customer base, right?</p> <p>10 A. Yes.</p> <p>11 Q. And I'm just going to call to</p> <p>12 your attention "Phase III: Utilize chargeback</p> <p>13 and IMS data to 'know your customer's</p> <p>14 customer'," correct?</p> <p>15 A. That's what it says, yes.</p> <p>16 Q. Before you sat with the DEA?</p> <p>17 A. Yes.</p> <p>18 MS. VANNI: Object to form.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. One of the things in your phase</p> <p>21 planned approach here was to utilize chargeback</p> <p>22 and IMS data so that you could know your</p> <p>23 customer's customer, correct?</p> <p>24 MS. VANNI: Object to form.</p>	<p style="text-align: right;">Page 385</p> <p>1 (Brief recess.)</p> <p>2 THE VIDEOGRAPHER: We're now back</p> <p>3 on the record. The time is 3:39 p m.</p> <p>4 (Document marked for</p> <p>5 identification as Par-Norton Deposition</p> <p>6 Exhibit No. 17.)</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. Ma'am, I'm passing you over what</p> <p>9 we're marking as Exhibit 17 to your deposition.</p> <p>10 Are you miked up, ma'am?</p> <p>11 A. Yes.</p> <p>12 Q. You are. Okay. Better than I.</p> <p>13 It's a document from early 2013,</p> <p>14 right?</p> <p>15 A. Yes.</p> <p>16 Q. An e-mail from yourself to Sanjay</p> <p>17 Patel?</p> <p>18 A. Yes, correct.</p> <p>19 Q. Copied to your boss, Jill</p> <p>20 Connell?</p> <p>21 A. Yes.</p> <p>22 Q. Was Sanjay also your boss?</p> <p>23 A. He was when Jill left the</p> <p>24 company, Sanjay was my boss.</p>

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<p style="text-align: right;">Page 386</p> <p>1 Q. Okay. This is today's meeting, 2 and then it's got a list of action items. 3 Do you see that? 4 A. Yes, I do. 5 Q. Okay. Let's roll forward to the 6 body of this, and it's January 4, 2013, just to 7 orient ourselves in time. This would have been 8 prior to the meeting with DEA when you got that 9 thick binder that we spoke about, right? 10 A. Yes. 11 Q. This would have been prior to the 12 interactions you had with the Buzzeo group in 13 mid-January 2013, right? 14 A. Yes. 15 Q. Okay. Let's go forward to -- if 16 we could, page 574.24, right. 17 So prior to this meeting and this 18 audit you had with Buzzeo, you were categorizing 19 potential failure modes and effects, visibility 20 rating, severity rating, et cetera, right? 21 A. Yes. 22 Q. Okay. And so with regard to your 23 suspicious order monitoring system, you note 24 that it was built in pieces and only applies to</p>	<p style="text-align: right;">Page 388</p> <p>1 Q. Not good, right? 2 MS. VANNI: Objection. 3 THE WITNESS: Not good. 4 BY MR. BUCHANAN: 5 Q. Okay. "The system needs to be 6 revamped," right? 7 A. Yes. 8 Q. Remember we talked earlier about 9 the system needing to be revamped? 10 A. Yes, improvements needed to be 11 made. 12 Q. And what you wrote was revamped, 13 right? 14 MS. VANNI: Object to form. 15 THE WITNESS: Yes. 16 BY MR. BUCHANAN: 17 Q. First, all customers have to be 18 added, right? 19 A. Yes. 20 Q. "IMS data and chargeback data 21 incorporated," correct? 22 A. That's what it says, yes. 23 Q. "And eventually a contracted 24 customer assessment firm hired or an on-site</p>
<p style="text-align: right;">Page 387</p> <p>1 the retail side of the business, correct, ma'am? 2 A. SOMS does, yes. 3 Q. Okay. The "suspicious order 4 monitoring program was built in pieces and only 5 applies to the retail side of the business." 6 Did I read that correctly? 7 A. You did. 8 Q. DEA requires it to apply to all 9 customers. 10 Do you see that? 11 A. Correct, which is what we had -- 12 Q. Your words, right? 13 A. Yes. 14 Q. Okay. "In addition, the current 15 system has had two issues in the past year that 16 resulted in controlled product being released 17 that should not have been." 18 Do you see that? 19 A. Yes, I do. 20 Q. That's not good, right? 21 MS. VANNI: Object to form. 22 THE WITNESS: That's what it 23 says, yes. 24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 389</p> <p>1 SOMS specific individual to perform these 2 assessments." 3 Did I read that correctly? 4 A. Yes, you did. 5 Q. You knew all of that on your own 6 without having to go up to DC and meet with the 7 DEA, right? 8 MS. VANNI: Object to form. 9 THE WITNESS: Yes, we were trying 10 to make a lot of improvements before DEA 11 even got involved. 12 BY MR. BUCHANAN: 13 Q. Okay. How to revamp it, right? 14 A. How to make improvements. 15 Q. Okay. And previously you 16 characterized the old system as inadequate, 17 correct? 18 MS. VANNI: Object to form. 19 THE WITNESS: Yes. 20 BY MR. BUCHANAN: 21 Q. Okay. Then we look at visibility 22 rating and severity rating, right? 23 A. Yes. 24 Q. You've been in corporate land for</p>

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<p style="text-align: right;">Page 390</p> <p>1 a while, right?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: Yes.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. This is one way you do a risk</p> <p>6 assessment, right?</p> <p>7 A. Yes.</p> <p>8 Q. Look at the visibility of the</p> <p>9 problem, look at the severity of the problem and</p> <p>10 then give it a risk score, right?</p> <p>11 A. Correct.</p> <p>12 Q. And the risk score you gave this</p> <p>13 for visibility was a 5, right?</p> <p>14 A. Yes.</p> <p>15 Q. And severity was a 5, right?</p> <p>16 A. Yes.</p> <p>17 Q. And the total risk rating was 25,</p> <p>18 right?</p> <p>19 A. Yes.</p> <p>20 Q. Highest of anything -- highest of</p> <p>21 any risk, right?</p> <p>22 MS. VANNI: Objection.</p> <p>23 THE WITNESS: Twenty-five was the</p> <p>24 highest in the document, mm-hmm.</p>	<p style="text-align: right;">Page 392</p> <p>1 Q. And not just your people, I mean</p> <p>2 all Qualitest employees?</p> <p>3 A. To train the company.</p> <p>4 Q. Right.</p> <p>5 A. It wasn't that they hadn't</p> <p>6 received any training, there just wasn't any</p> <p>7 training that was mandated by the company for</p> <p>8 employees and nothing on a routine basis.</p> <p>9 Q. 574.29, additional failure modes</p> <p>10 and effects, again, with regard to controlled</p> <p>11 substances, this relates to checking</p> <p>12 registrations on orders.</p> <p>13 Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Currently, the</p> <p>16 registrations are checked when somebody becomes</p> <p>17 a new customer, right?</p> <p>18 A. Yes.</p> <p>19 Q. And when I say "currently," I</p> <p>20 mean when you were writing this in early 2013?</p> <p>21 A. Yes, that's correct.</p> <p>22 Q. Okay. And then they were only</p> <p>23 done every year after that, correct?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 391</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Thank you.</p> <p>3 Let's go to 574.28. Potential</p> <p>4 failure mode and effect, "No mandatory, routine</p> <p>5 DEA training exists for employees handling</p> <p>6 controlled substances."</p> <p>7 Did I read that correctly?</p> <p>8 A. Yes.</p> <p>9 Q. And, again, 70% of the business</p> <p>10 of Qualitest was controlled substances, right?</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: Yes.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. "Knowledge of DEA regulations is</p> <p>15 not incorporated into employee's job</p> <p>16 descriptions or performance reviews," correct?</p> <p>17 A. Correct.</p> <p>18 Q. At this point in time, resources</p> <p>19 were prohibitive to train all employees, right?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And one of the things you</p> <p>22 were doing was to look for some funding so you</p> <p>23 could train your people, right?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 393</p> <p>1 Q. And what was the industry</p> <p>2 standard at that point in time, ma'am?</p> <p>3 A. I don't know. I don't think</p> <p>4 everybody was using NTIS, but I don't know for</p> <p>5 sure.</p> <p>6 Q. Well, let's see what you wrote.</p> <p>7 What did you write the industry</p> <p>8 standard was at that point in time?</p> <p>9 A. "Industry standard is now to</p> <p>10 check the DEA license at each purchase since</p> <p>11 shipping to an entity that has an expired or</p> <p>12 invalid license is a \$10,000 fine."</p> <p>13 Q. Okay. And then you note, "The</p> <p>14 capability exists to automate this check at the</p> <p>15 weekly level (NTIS Tape or Database)" and "We</p> <p>16 need to check registrations more frequently,"</p> <p>17 right?</p> <p>18 A. Yes, that's what I wanted.</p> <p>19 Q. Does this refresh your memory as</p> <p>20 to what you characterized the industry standard</p> <p>21 to be?</p> <p>22 A. It does, yes.</p> <p>23 Q. Okay. And, in fact, when you</p> <p>24 were back at Ciba-Geigy and Novartis and they</p>

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<p style="text-align: right;">Page 394</p> <p>1 were already using the NTIS data, right --</p> <p>2 A. They did.</p> <p>3 Q. -- back in the '80s and '90s?</p> <p>4 A. They did.</p> <p>5 Q. And when you were at Watson, they</p> <p>6 were using, it right?</p> <p>7 A. Yes.</p> <p>8 Q. And in this 2012, 2013 period you</p> <p>9 had the situation where controlled substances</p> <p>10 were released to customers who should not -- who</p> <p>11 they should not have been released to, correct?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: That was not -- I</p> <p>14 don't believe that was in relation to</p> <p>15 their license.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Oh, okay. What was it in</p> <p>18 relation to?</p> <p>19 A. I don't know if it was -- I don't</p> <p>20 know why. I need to go back to see it.</p> <p>21 Q. Sitting here, do you have a</p> <p>22 recollection?</p> <p>23 A. I do not.</p> <p>24 Q. If you don't, I'm sorry, I'm just</p>	<p style="text-align: right;">Page 396</p> <p>1 might be there when there's a DEA inspection of</p> <p>2 a manufacturing facility, for example, right?</p> <p>3 A. Correct, and I would summarize</p> <p>4 each day.</p> <p>5 Q. Right. And so you'd send around</p> <p>6 a report to the team or management about the</p> <p>7 results of the inspection, right?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And so this was an</p> <p>10 inspection of a manufacturing facility as the</p> <p>11 primary purpose, correct?</p> <p>12 A. In Charlotte, yes.</p> <p>13 Q. And you'd had an issue with</p> <p>14 Charlotte previously, right?</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: Yes, it was</p> <p>17 manufacturing.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. And, basically, you had raw</p> <p>20 material that was unaccounted for.</p> <p>21 Do you remember that?</p> <p>22 MS. VANNI: Object to form.</p> <p>23 THE WITNESS: I do not, but if</p> <p>24 you give me a minute, I'll look at this.</p>
<p style="text-align: right;">Page 395</p> <p>1 going to do my best to move along.</p> <p>2 A. Okay.</p> <p>3 Q. Because I try not to go down too</p> <p>4 many forks in the road, if you don't mind.</p> <p>5 A. Got it.</p> <p>6 Q. All right. So let's dial back</p> <p>7 the clock, if we could.</p> <p>8 MR. BUCHANAN: Could I have 567.</p> <p>9 (Document marked for</p> <p>10 identification as Par-Norton Deposition</p> <p>11 Exhibit No. 18.)</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. Passing you what we're marking as</p> <p>14 Exhibit 18 to your deposition, ma'am. It's an</p> <p>15 exchange, it looks like right after you get to</p> <p>16 the company in 2011. It's 567. It should be on</p> <p>17 the screen, hopefully.</p> <p>18 You see this e-mail exchange</p> <p>19 between yourself and others relating to a DEA</p> <p>20 inspection at one of your facilities?</p> <p>21 A. Yes, I do.</p> <p>22 Q. Okay. Let's -- I'd like to</p> <p>23 direct your attention -- this is one of the</p> <p>24 things you would do with DEA compliance. You</p>	<p style="text-align: right;">Page 397</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Okay. Let me just try to keep us</p> <p>3 focused, I'm sorry, if that's going to require</p> <p>4 you to go elsewhere.</p> <p>5 A. Okay.</p> <p>6 Q. 567.2, middle of the second page,</p> <p>7 and there's this discussion here with the</p> <p>8 paragraph beginning he noted about, you know,</p> <p>9 material not being accounted for, you know, if</p> <p>10 you have .15% that's not accounted for, given</p> <p>11 the volume of controlled substances y'all were</p> <p>12 making and that turns into 130 pounds worth of</p> <p>13 raw material, controlled substances, right?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: Mm-hmm.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. So you've got 130 pounds of raw</p> <p>18 materials that aren't accounted for, and you</p> <p>19 guys need to tighten up your process to make</p> <p>20 sure 130 pounds of -- this says 64 kilograms,</p> <p>21 that's, you know -- that's about 130 pounds,</p> <p>22 right?</p> <p>23 A. Calculation.</p> <p>24 Q. Okay. 135, something like that?</p>

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<p style="text-align: right;">Page 398</p> <p>1 A. Mm-hmm.</p> <p>2 Q. Okay. He went on to say that</p> <p>3 "manufacturers are making larger batch sizes and</p> <p>4 greater quantities of controlled product than in</p> <p>5 years past," right?</p> <p>6 A. Yes.</p> <p>7 Q. I mean, you guys were making a</p> <p>8 lot of pills, no debate about that, right?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: That is what it</p> <p>11 says.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. It says, "DEA is seeing a much</p> <p>14 higher rate of prescription drug abuse and</p> <p>15 diversion as compared to illicit drugs now."</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Higher rate of prescription drug</p> <p>19 abuse and diversion as compared to illicit drugs</p> <p>20 now, and now being 2011, right?</p> <p>21 A. Yes.</p> <p>22 Q. And this is a couple years</p> <p>23 before --</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 400</p> <p>1 A. I do.</p> <p>2 Q. And do you agree, ma'am, that as</p> <p>3 a registrant manufacturer and a registrant</p> <p>4 distributor that you have the public's trust in</p> <p>5 your hands?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: We have a</p> <p>8 responsibility to abide by the</p> <p>9 regulations, the DEA regulations.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Right. You have a responsibility</p> <p>12 under the statute to maintain effective controls</p> <p>13 against diversion?</p> <p>14 A. Right.</p> <p>15 Q. And would you fault people of the</p> <p>16 public, knowing that you have that obligation,</p> <p>17 for assuming that you were going to do</p> <p>18 everything in your power to maintain effective</p> <p>19 controls against diversion?</p> <p>20 MS. VANNI: Objection.</p> <p>21 THE WITNESS: That is what we</p> <p>22 did.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Would you fault people for</p>
<p style="text-align: right;">Page 399</p> <p>1 Q. Thank you.</p> <p>2 It's a couple years before you</p> <p>3 had that sit down with the DEA where you got</p> <p>4 called into DC, right?</p> <p>5 A. Yes.</p> <p>6 MS. VANNI: Object to form.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. Okay. So you had that knowledge</p> <p>9 certainly in 2011, right, ma'am?</p> <p>10 MS. VANNI: Object to form.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. Okay. He stated -- he states,</p> <p>14 "Yet, in his opinion, nothing has changed on the</p> <p>15 manufacturer's side in regards to the way we do</p> <p>16 reconciliations."</p> <p>17 Do you see that?</p> <p>18 A. Yes, I do.</p> <p>19 Q. "He stated that we have the</p> <p>20 public's trust in our hands and we need to be</p> <p>21 sure we are staying ahead of the curve by</p> <p>22 monitoring current diversion trends and</p> <p>23 tightening our processes."</p> <p>24 Do you see that?</p>	<p style="text-align: right;">Page 401</p> <p>1 expecting that of you?</p> <p>2 MS. VANNI: Objection.</p> <p>3 THE WITNESS: No.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. That's what you should do, right?</p> <p>6 MS. VANNI: Objection.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. And let's turn now to the next</p> <p>10 page, point three, it says, "DEA then spoke</p> <p>11 about SOMS at length and also discussed the need</p> <p>12 to monitor customers (wholesalers in</p> <p>13 particular), including our wholesaler's</p> <p>14 customers, through periodic audits or on-site</p> <p>15 visits," correct?</p> <p>16 A. Yes.</p> <p>17 Q. "This is not something we are</p> <p>18 currently doing and another item we will need to</p> <p>19 work on improving."</p> <p>20 Did I read that correctly?</p> <p>21 A. You did.</p> <p>22 Q. And so two years or so before</p> <p>23 back in 2011, before -- long before you sat down</p> <p>24 with the DEA in DC, you were told you got to</p>

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<p style="text-align: right;">Page 402</p> <p>1 monitor your customers, wholesalers in 2 particular, but including your wholesaler's 3 customers, right? 4 MS. VANNI: Object to form. 5 THE WITNESS: Yes, and we were 6 not as part of SOMS, we were as part of 7 OMS, at least the wholesalers. 8 BY MR. BUCHANAN: 9 Q. Okay. And it would be fair to 10 say, ma'am, sitting here today, you're not aware 11 of a single site visit report of wholesaler that 12 was done through OMS, right? 13 MS. VANNI: Objection. 14 THE WITNESS: I am not, but that 15 doesn't mean they didn't occur. 16 BY MR. BUCHANAN: 17 Q. Okay. And we looked at the 18 inadequate -- the inadequacies of the system -- 19 A. We looked at -- 20 Q. -- in your earlier documents. Do 21 you recall looking at that? 22 MS. VANNI: Object to form. 23 THE WITNESS: The improvements 24 we'd like to make, yes.</p>	<p style="text-align: right;">Page 404</p> <p>1 on-site visits that this is not something you 2 were currently doing, right? 3 A. Not something we were currently 4 doing under SOMS. 5 Q. That's not what you wrote. We 6 can agree on that, right? 7 MS. VANNI: Objection. 8 THE WITNESS: That's not what's 9 written. 10 BY MR. BUCHANAN: 11 Q. And what you follow with that is 12 "another item we will need to work on 13 improving." 14 Did I read that correctly? 15 A. You did. 16 Q. An item you will need to work on 17 improving. Not that we're doing it through 18 customer service, right? 19 MS. VANNI: Objection. 20 THE WITNESS: No, that's not what 21 it says. I didn't elaborate. 22 BY MR. BUCHANAN: 23 Q. Not that you were doing it 24 through sales?</p>
<p style="text-align: right;">Page 403</p> <p>1 BY MR. BUCHANAN: 2 Q. I think you called them 3 inadequacies, right? 4 A. In the document. 5 Q. Yes. 6 A. But it means improvements. 7 Q. Well, let's not talk about what 8 you say it means today. Let's talk about what 9 you wrote. 10 You wrote inadequate, correct? 11 MS. VANNI: Objection. 12 THE WITNESS: I did. 13 BY MR. BUCHANAN: 14 Q. Thank you. 15 And you said this is not 16 something we are currently doing, right? 17 A. Not in SOMS. 18 Q. What you wrote here, ma'am, after 19 the DEA spoke about SOMS at length and also 20 discussed the need to monitor customers, 21 wholesalers in particular, including our 22 wholesaler's customers -- 23 A. Yes. 24 Q. -- through periodic audits and</p>	<p style="text-align: right;">Page 405</p> <p>1 MS. VANNI: Objection. 2 THE WITNESS: This group is the 3 manufacturing group. I would not have 4 gone into detail about our SOM program 5 with that group. 6 BY MR. BUCHANAN: 7 Q. Right, and, certainly, what you 8 said was it's not something you're currently 9 doing? We could agree that's what you wrote, 10 correct? 11 A. That is what it says. 12 MS. VANNI: Objection, asked and 13 answered now about ten times. 14 MR. BUCHANAN: Okay. Let's go 15 to -- I don't think it was ten, but it 16 may have been more than one. 17 THE WITNESS: Nine and a half. 18 MR. BUCHANAN: Let's go to 1046. 19 (Document marked for 20 identification as Par-Norton Deposition 21 Exhibit No. 19.) 22 BY MR. BUCHANAN: 23 Q. Passing you Exhibit 19. I 24 probably should have done this -- kind of I'm</p>

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<p style="text-align: right;">Page 406</p> <p>1 working back in time, if you can follow where 2 we're going, ma'am. We first -- we just looked 3 at an early 2013 exchange where you had a 25 4 risk assessment for your SOMS program. 5 Do you recall that? 6 A. Yes. 7 Q. Twenty-five being the worst, 8 right? 9 A. Being -- yes, the highest 10 priority -- 11 MS. VANNI: Object to form. 12 THE WITNESS: -- that I want to 13 work on. 14 BY MR. BUCHANAN: 15 Q. Yeah, and then we also looked at 16 kind of that -- your closeout memo from that DEA 17 inspection in Charlotte. That was 2011, right? 18 A. Mm-hmm, yes. 19 Q. Yes? 20 A. Yes. 21 Q. I'm a little out of sequence 22 here. This one is September 2012. For the 23 record, I think we're on Exhibit 19. 24 And this is an e-mail from</p>	<p style="text-align: right;">Page 408</p> <p>1 Did I read that correctly? 2 A. "We just need to do our due 3 diligence to find out what happens," yes. 4 Q. Right. "We just need to do our 5 due diligence to find out what happens to our 6 product beyond the first level of the supply 7 chain," right? 8 A. For this particular customer, 9 yes, that's what I'm referring to. 10 Q. So your supply chain, your supply 11 chain first level would be wholesalers 12 distributors, right? 13 A. Yes. 14 Q. Supply chain beyond the first 15 level would be the people they sell to, right? 16 A. Correct. 17 Q. People they sell to might be 18 pharmacies, might be hospitals, any number of 19 places, right? 20 A. Yes. 21 Q. And so with this saying you got 22 to do your due diligence to find out what 23 happens to your product beyond the first level 24 of the supply chain, right?</p>
<p style="text-align: right;">Page 407</p> <p>1 yourself to Eric Bonner. Who is Eric Bonner? 2 A. That's our -- was the plant 3 manager. 4 Q. Okay. And there's a press 5 release that's out there about CVS retailers and 6 their ability to sell controlled substances, 7 right? 8 A. Yes. 9 Q. Okay. And you're directing them 10 to take -- make sure that they get taken out of 11 the order system, okay? 12 A. Right. 13 Q. Because they don't have licenses 14 anymore, right? 15 A. That's what we would do if DEA 16 had an issue with a customer, yes. 17 Q. Right. So now you couldn't 18 legally sell to somebody who doesn't have a 19 registration, right? 20 A. That's true. 21 Q. Okay. And then up top you say, 22 we need our due diligence to find out what 23 happens to our product beyond the first level of 24 the supply chain.</p>	<p style="text-align: right;">Page 409</p> <p>1 A. Yes. 2 Q. Because the DEA is no longer 3 buying that it's not you? 4 MS. VANNI: Object to form. 5 BY MR. BUCHANAN: 6 Q. Right? 7 A. I'm not getting what you're 8 referring to. 9 Q. Withdrawn, okay. 10 The DEA is no longer buying what 11 you all have been selling for years, right? 12 MS. VANNI: Objection. 13 THE WITNESS: No. 14 BY MR. BUCHANAN: 15 Q. What you all have been selling 16 for years was it wasn't us, it was our customer? 17 A. We don't sell -- 18 MS. VANNI: Objection. 19 THE WITNESS: -- anything to DEA. 20 BY MR. BUCHANAN: 21 Q. Well, I'm saying -- okay. Let's 22 look at what you wrote, ma'am. 23 A. Are you referring to 24 manufacturers in general? I mean, that's an odd</p>

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<p style="text-align: right;">Page 410</p> <p>1 statement.</p> <p>2 Q. I'm referring to what you wrote</p> <p>3 in the middle, September 12, 2012, if we ship to</p> <p>4 a distribution center -- that's what DC means,</p> <p>5 right?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. "That then further</p> <p>8 distributes to these registrants, we are still</p> <p>9 shipping to an entity that is contributing to</p> <p>10 diversion and abuse as evidenced by DEA pulling</p> <p>11 their license."</p> <p>12 Did I read that correctly?</p> <p>13 A. Yes.</p> <p>14 Q. "DEA is no longer buying the" --</p> <p>15 and then you put in quotes -- "it wasn't us, it</p> <p>16 was our customer philosophy," right?</p> <p>17 A. Yes, and that's --</p> <p>18 Q. I'm sorry. That's what you</p> <p>19 wrote, correct?</p> <p>20 A. Yes, that's what I wrote.</p> <p>21 MR. BUCHANAN: Can I have 1051,</p> <p>22 please.</p> <p>23 (Document marked for</p> <p>24 identification as Par-Norton Deposition</p>	<p style="text-align: right;">Page 412</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Okay. So, as I understand it,</p> <p>3 Qualitest was acquired by Endo, correct?</p> <p>4 A. Correct.</p> <p>5 Q. You joined Qualitest in 2011?</p> <p>6 A. Yes.</p> <p>7 Q. As part of your evaluation and</p> <p>8 role -- I'm sorry -- as part of your role in DEA</p> <p>9 compliance, did you look to see -- did you</p> <p>10 evaluate the department?</p> <p>11 A. Yes.</p> <p>12 MS. KOSKI: Object to form.</p> <p>13 THE WITNESS: To what extent?</p> <p>14 What are you referring to specifically</p> <p>15 did I evaluate?</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Well, would it surprise you that,</p> <p>18 in fact, Qualitest had other consultants come in</p> <p>19 years before you arrived and look at their</p> <p>20 suspicious order monitoring system?</p> <p>21 MS. VANNI: Objection.</p> <p>22 THE WITNESS: I don't know.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Okay. Here's a -- here is one</p>
<p style="text-align: right;">Page 411</p> <p>1 Exhibit No. 20.)</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. And that was 2011 -- 2012, excuse</p> <p>4 me?</p> <p>5 A. 2012.</p> <p>6 Q. So, again, once again, before you</p> <p>7 met with the DEA and had that sit down, right?</p> <p>8 A. Yes, to individuals that wouldn't</p> <p>9 understand the SOM program. These are basically</p> <p>10 operations people, so that's why it was worded</p> <p>11 that way.</p> <p>12 Q. Passing you, ma'am, what we've</p> <p>13 marked as Exhibit 20 to your -- I'm sorry, is</p> <p>14 this 20? Twenty. Let me read your sticker on</p> <p>15 the bottom right, ma'am.</p> <p>16 A. Exhibit 20.</p> <p>17 Q. I did do that right. Exhibit 20.</p> <p>18 MS. VANNI: I just want to lodge</p> <p>19 an objection to the use of this exhibit</p> <p>20 as it's before Endo's acquisition of</p> <p>21 Qualitest.</p> <p>22 MR. BUCHANAN: Okay.</p> <p>23 THE WITNESS: Yeah, and before my</p> <p>24 time at Qualitest as well.</p>	<p style="text-align: right;">Page 413</p> <p>1 such evaluation from 2008. Do you know John</p> <p>2 Schultz?</p> <p>3 A. Yes.</p> <p>4 Q. Who is John?</p> <p>5 A. He had the position before me.</p> <p>6 Q. Okay. So he was predecessor. He</p> <p>7 didn't have the name of head of DEA compliance,</p> <p>8 but he had a similar function?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: I'm not sure his</p> <p>11 title.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. Okay. "All, attached is Mike's</p> <p>14 audit report from his visit. We will need to</p> <p>15 formulate a response and implement the</p> <p>16 corrective actions. Please provide comment on</p> <p>17 the observations with suggested corrective</p> <p>18 actions."</p> <p>19 Did I read that correctly?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And, time permitting, we</p> <p>22 would get more deeply into this, but let's focus</p> <p>23 on the thread we're now talking about, 1051.2.</p> <p>24 Under the "Details" at the</p>

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<p style="text-align: right;">Page 414</p> <p>1 bottom, the issues that were noted during the</p> <p>2 review were, and then it's got paragraphs</p> <p>3 similar to what you've seen in the Buzzee one</p> <p>4 from during your time, right?</p> <p>5 MS. VANNI: Objection.</p> <p>6 THE WITNESS: Okay.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. The issues that were noted during</p> <p>9 the review were, "1. Reporting of Suspicious</p> <p>10 Orders to DEA, in addition to reporting</p> <p>11 Suspicious Sales."</p> <p>12 Do you see that?</p> <p>13 A. I do.</p> <p>14 MR. BUCHANAN: Sorry, Bradley,</p> <p>15 you have to be on 1051.2.</p> <p>16 TRIAL TECHNICIAN: I am.</p> <p>17 MR. BUCHANAN: And scroll down to</p> <p>18 the issues that were noted during the</p> <p>19 review were 1, I'm sorry, above. There</p> <p>20 you go. Thanks. We're going to scroll</p> <p>21 down.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. It continues now on the body</p> <p>24 under details, "A check with Mr. Schultz showed</p>	<p style="text-align: right;">Page 416</p> <p>1 Q. And oxycodone -- there's a</p> <p>2 reference to where they come from. They come</p> <p>3 from the company's files.</p> <p>4 MS. VANNI: Objection.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. And then there's, what, about</p> <p>7 89 million oxycodone pills, right?</p> <p>8 A. That's what it says, yes.</p> <p>9 Q. So enough to give a handful of</p> <p>10 controlled substances to every human being in</p> <p>11 the United States of America, right?</p> <p>12 MS. VANNI: Objection.</p> <p>13 THE WITNESS: I don't know.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Okay. During this period of</p> <p>16 time, you were told the Qualitest system for</p> <p>17 reporting suspicious orders to DEA needs to be</p> <p>18 improved, right?</p> <p>19 MS. LEIBELL: Object to form.</p> <p>20 THE WITNESS: This is before I</p> <p>21 got there. I was not told anything</p> <p>22 about this.</p> <p>23 MS. VANNI: Are you referring to</p> <p>24 the 2008 period?</p>
<p style="text-align: right;">Page 415</p> <p>1 that in the past eight months no reports of</p> <p>2 suspicious orders were sent to DEA," correct?</p> <p>3 A. That's what it says, yes.</p> <p>4 Q. And we looked at that chart</p> <p>5 earlier concerning product that was shipped, and</p> <p>6 do you still have Exhibit 4 in the general</p> <p>7 vicinity over there, ma'am.</p> <p>8 A. Exhibit 4?</p> <p>9 Q. Looks like -- yeah, looks like in</p> <p>10 2008 --</p> <p>11 A. The quantities.</p> <p>12 Q. -- Qualitest shipped, and this is</p> <p>13 from 2008, right?</p> <p>14 MS. VANNI: Is this your</p> <p>15 demonstrative?</p> <p>16 MR. BUCHANAN: It is. Well, it's</p> <p>17 what you've pointed us to.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Looking at 2008 we see some,</p> <p>20 what, 1.7 billion pills of hydrocodone products,</p> <p>21 right?</p> <p>22 A. That's what your document says,</p> <p>23 but, again, I don't know where those numbers</p> <p>24 come from or what detail.</p>	<p style="text-align: right;">Page 417</p> <p>1 MR. BUCHANAN: I am. So I'm</p> <p>2 referring to the 2008, the inspection</p> <p>3 and report, okay.</p> <p>4 MS. VANNI: So it was prior to</p> <p>5 Endo's acquisition and prior to the</p> <p>6 witness' employment with Qualitest.</p> <p>7 THE WITNESS: Right.</p> <p>8 MS. VANNI: Just note my</p> <p>9 objection.</p> <p>10 MR. BUCHANAN: Those are points</p> <p>11 that you can note, certainly. I don't</p> <p>12 think they impede or otherwise undermine</p> <p>13 the relevancy.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. On the bottom of 1051.3 it says,</p> <p>16 "It is important to Qualitest to work with all</p> <p>17 controlled substance customers, including those</p> <p>18 who will further distribute Qualitest products</p> <p>19 to other DEA registrants, to assure that the</p> <p>20 controlled substances are distributed only to</p> <p>21 customers who have systems in place to assure</p> <p>22 that the controlled substances will be used for</p> <p>23 legitimate medical purposes."</p> <p>24 Do you see that, ma'am?</p>

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<p style="text-align: right;">Page 418</p> <p>1 A. I see it.</p> <p>2 Q. And this is 2008, correct?</p> <p>3 A. That's the date on it.</p> <p>4 Q. You can set that aside.</p> <p>5 A. Again, I had no knowledge of it</p> <p>6 and wasn't involved.</p> <p>7 Q. Okay. And, again, we looked at a</p> <p>8 letter from Mr. Rannazzisi in a PowerPoint.</p> <p>9 Do you recall that?</p> <p>10 A. Yes.</p> <p>11 Q. That was from 2007?</p> <p>12 A. Correct.</p> <p>13 Q. Okay. Let's try and move</p> <p>14 forward.</p> <p>15 In late 2013 the company revamped</p> <p>16 its SOMS process and implemented new SOPs, fair?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 THE WITNESS: Upgraded the</p> <p>19 program, yes.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. And I don't think we'll have time</p> <p>22 to go through those SOPs with you, but I would</p> <p>23 like to talk to you about some of the responses</p> <p>24 you received to the dear customer letter, the</p>	<p style="text-align: right;">Page 420</p> <p>1 (Document marked for</p> <p>2 identification as Par-Norton Deposition</p> <p>3 Exhibit No. 21.)</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. Passing you what we're marking as</p> <p>6 Exhibit 21 to your deposition, ma'am, it's an</p> <p>7 exchange with you and your SOMS coordinator,</p> <p>8 Mr. Brantley.</p> <p>9 A. Okay.</p> <p>10 Q. This is from late 2014 or October</p> <p>11 of 2014, and I guess if you start back forward,</p> <p>12 you'll see an exchange between Mr. Brantley and</p> <p>13 Mr. Kent with his att net e-mail address for</p> <p>14 Preferred Pharmaceuticals in response to</p> <p>15 Mr. Brantley's inquiries.</p> <p>16 Do you see that?</p> <p>17 A. I do.</p> <p>18 Q. Okay.</p> <p>19 MR. BUCHANAN: Please, Bradley,</p> <p>20 go to 1075.4, just so we're following</p> <p>21 each other on the screen.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. All right. There we go, we see</p> <p>24 the e-mail from Mr. Kent for Preferred</p>
<p style="text-align: right;">Page 419</p> <p>1 responses you didn't receive, okay?</p> <p>2 A. Okay.</p> <p>3 MR. BUCHANAN: Can I have 1075,</p> <p>4 please.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Who is Preferred Pharmaceuticals?</p> <p>7 A. I don't recall.</p> <p>8 Q. Does the name ring a bell to you?</p> <p>9 A. No, it does not.</p> <p>10 Q. Okay. Let's kind of reorient</p> <p>11 ourselves.</p> <p>12 In 2013 after everything we've</p> <p>13 discussed, after the risk assessment you set</p> <p>14 forward, after some meetings with management,</p> <p>15 after procuring some resources and getting</p> <p>16 consent from others, you sent a letter out to</p> <p>17 customers, right?</p> <p>18 A. Yes.</p> <p>19 Q. Those customers included</p> <p>20 distributors, those customers included some end</p> <p>21 user pharmacies that were dealing direct with</p> <p>22 the company, and you got responses from many of</p> <p>23 those customers, right?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 421</p> <p>1 Pharmaceuticals, and Mr. Brantley is having a</p> <p>2 back-and-forth with them concerning his -- part</p> <p>3 of the due diligence process that's described in</p> <p>4 your revamped SOPs, correct?</p> <p>5 A. Yes.</p> <p>6 Q. Part of what you implemented in</p> <p>7 late 2013, correct?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: I'm sorry? I'm</p> <p>10 sorry, I was reading.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. You know what, fair.</p> <p>13 So in late 2013 you revamped your</p> <p>14 SOMS process, correct?</p> <p>15 MS. VANNI: Form.</p> <p>16 THE WITNESS: We made upgrades to</p> <p>17 it starting --</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Letters went out, correct?</p> <p>20 A. Letters went out then, yes.</p> <p>21 Q. Mr. Brantley conducted some due</p> <p>22 diligence visits, correct?</p> <p>23 A. Yes.</p> <p>24 Q. Mr. Brantley also engaged with</p>

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<p style="text-align: right;">Page 422</p> <p>1 customers to get verification that they actually</p> <p>2 had a SOM program, right?</p> <p>3 A. Yes.</p> <p>4 Q. Because this was close --</p> <p>5 A. All ongoing.</p> <p>6 Q. This closed system doesn't work</p> <p>7 if the people you're selling to really aren't</p> <p>8 watching their customers, right?</p> <p>9 MS. VANNI: Object to form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Okay. So Mr. Brantley sent some</p> <p>13 follow-up questions to Mr. Kent, and he sends to</p> <p>14 you 1075.2. "Tracey, please see the response</p> <p>15 below from Preferred Pharmaceuticals."</p> <p>16 Do you see that, 1075.2? That's</p> <p>17 also on the screen, if that's easier for you.</p> <p>18 A. No, it's okay.</p> <p>19 Yes.</p> <p>20 Q. Okay. And then you send a</p> <p>21 response back to Mr. Brantley, and that's at the</p> <p>22 bottom of 1075.1.</p> <p>23 A. Okay.</p> <p>24 Q. Subject: external, Due Diligence</p>	<p style="text-align: right;">Page 424</p> <p>1 A. You did.</p> <p>2 Q. Okay. So you're getting</p> <p>3 information from a customer who is a smaller</p> <p>4 distributor, right?</p> <p>5 A. Mm-hmm.</p> <p>6 Q. Certainly one that didn't come</p> <p>7 front of mind when I mentioned it to you,</p> <p>8 Preferred Pharmaceuticals?</p> <p>9 A. No, it did not. I mean, Eric was</p> <p>10 really the main customer facing person.</p> <p>11 Q. I understand, but, you know, a</p> <p>12 distributor that's working with smaller volumes,</p> <p>13 right, correct?</p> <p>14 A. I believe. I don't know if</p> <p>15 they're a distributor, a pharmacy, I'm not sure.</p> <p>16 Q. [REDACTED]</p> <p>17 [REDACTED]?</p> <p>18 A. I have one -- I have high</p> <p>19 expectations for the customer as well as us,</p> <p>20 yes.</p> <p>21 Q. Right, right, and, in fact, we</p> <p>22 could agree that as it related to the other</p> <p>23 classes of trade, ma'am, prior to revamping the</p> <p>24 inadequate SOM system at Qualitest in 2013,</p>
<p style="text-align: right;">Page 423</p> <p>1 and Revised SOM. "Have him provide proof of</p> <p>2 recent (last two years) training in either SOMS</p> <p>3 diversion or abuse."</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. And these are your</p> <p>7 instructions back to your employee,</p> <p>8 Mr. Brantley, correct?</p> <p>9 A. Yes.</p> <p>10 Q. "Also, the 'new software' he</p> <p>11 refers to still does not sound like it evaluates</p> <p>12 the order [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 A. Yes.</p> <p>15 Q. "That function should not be done</p> <p>16 manually."</p> <p>17 Do you see that?</p> <p>18 A. Ideally, yes.</p> <p>19 Q. That's what you wrote, right?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. "Please push him for</p> <p>22 additional information on that; maybe he is just</p> <p>23 unsure what we are looking for."</p> <p>24 Did I read that correctly?</p>	<p style="text-align: right;">Page 425</p> <p>1 other classes of trade, if they were being done</p> <p>2 [REDACTED]?</p> <p>3 MR. SCHACK: Objection.</p> <p>4 MS. VANNI: Objection.</p> <p>5 THE WITNESS: No. It would have</p> <p>6 been done by our OMS program.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. Okay. Evaluating frequency, size</p> <p>9 and volume?</p> <p>10 A. [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 Q. Right. And so one of the things</p> <p>13 you're calling out your customer for in 2014 is</p> <p>14 it's got to evaluate frequency, size and volume,</p> <p>15 correct?</p> <p>16 A. It needs to address it so --</p> <p>17 Q. [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 A. Right.</p> <p>20 Q. Please push him for additional</p> <p>21 information on that, right?</p> <p>22 A. What he -- it looks like --</p> <p>23 Q. Is that what you --</p> <p>24 A. And I haven't had time to read</p>

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1 the full thing, but it looks like what he's  
2 saying is that [REDACTED]

4 Q. [REDACTED]

5 A. [REDACTED]

9 Q. Okay. Your system, as it related  
10 to other classes of trade, ma'am, was not  
11 looking at the other two, correct?

12 MS. VANNI: Object to form.

13 THE WITNESS: It was, just the  
14 system, the electronic computerized  
15 system was [REDACTED]

18 BY MR. BUCHANAN:

19 Q. You'd agree, ma'am, that a  
20 company that was making billions and billions  
21 and billions of pills was getting many more line  
22 items of orders from its customers than a  
23 company like Preferred Pharmaceuticals?

24 MS. VANNI: Objection.

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1 Q. It states, my concern is with the  
2 lack -- up top now, I'm sorry.

3 Okay. "My concern is with the  
4 lack of a program that reviews order frequency,  
5 pattern and volume. If he can't prove it to us,  
6 how will he prove it to DEA?"

7 Do you see that?

8 A. Yes.

9 Q. Okay. And so this is the process  
10 the company was undergoing, and you brought in  
11 Mr. Brantley in September of 2013, correct?

12 A. Yes.

13 Q. Going out to its customers and  
14 saying what are the processes you have in place,  
15 customer, correct?

16 A. Correct.

17 Q. We're going to make sure, as best  
18 we're able at this point in time --

19 A. Yes.

20 Q. -- to figure out whether you've  
21 got your head in the sand or whether you  
22 actually have a suspicious order monitoring  
23 program, right?

24 MS. VANNI: Objection.

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1 THE WITNESS: I don't know  
2 Preferred Pharmaceuticals' quantities to  
3 convey that.

4 BY MR. BUCHANAN:

5 Q. Okay. And then you said, please  
6 provide proof -- I'm sorry -- have him provide  
7 proof you said, right?

8 You see that?

9 A. Yes.

10 Q. Of recent last two years training  
11 in either SOMS diversion and abuse or abuse.  
12 Do you recall that?

13 A. Yes.

14 Q. And we saw your assessment from  
15 2013. Another of your risk areas was a lack of  
16 education within Qualitest?

17 MS. VANNI: Objection.

18 THE WITNESS: That was not  
19 related to SOMS.

20 BY MR. BUCHANAN:

21 Q. Okay.

22 A. That training was overall general  
23 DEA requirements, more recordkeeping, security  
24 and accountability based.

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1 THE WITNESS: Right.

2 BY MR. BUCHANAN:

3 Q. Okay. And that's necessary if  
4 we're going to maintain this closed system,  
5 right?

6 MS. VANNI: Objection.

7 THE WITNESS: Yes.

8 BY MR. BUCHANAN:

9 Q. Okay.

10 A. The level that we were asking for  
11 was not necessarily necessary, but to have a  
12 SOMS system was necessary.

13 Q. Well, what you said was you  
14 wanted proof, right? After that DEA meeting --

15 A. There's several things.

16 Q. -- in March of 2013, you wanted  
17 proof that he'd had it, right?

18 MS. VANNI: Object to form.

19 THE WITNESS: There are several  
20 things in here that I was asking for.

21 BY MR. BUCHANAN:

22 Q. Yeah, and, in fact, there'd been  
23 -- and we don't have time to go through it,  
24 there had been a back-and-forth with Preferred

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<p style="text-align: right;">Page 430</p> <p>1     Pharmaceuticals for -- this is about, what, a</p> <p>2     year after, this is a year after your first</p> <p>3     letter went out, right?</p> <p>4         A.   Uh-huh.</p> <p>5         Q.   So a year after your first letter</p> <p>6     goes out, you're still going back and forth with</p> <p>7     Preferred Pharma about whether they've got</p> <p>8     programs in place, right?</p> <p>9         MS. VANNI: Object to form.</p> <p>10        THE WITNESS: Well, keep in mind</p> <p>11        too when you send out a letter --</p> <p>12    BY MR. BUCHANAN:</p> <p>13        Q.   Is that correct?</p> <p>14        A.   -- you don't know -- I don't know</p> <p>15     how long this went on.</p> <p>16        Q.   Well, I'm sorry. This is --</p> <p>17        A.   I mean, this is 2014, but I don't</p> <p>18     know what happened from the time of the letter</p> <p>19     to this.</p> <p>20        Q.   October 21, 2014 --</p> <p>21        A.   Correct.</p> <p>22        Q.   -- correct, that's your last</p> <p>23     e-mail? You're still not satisfied that they've</p> <p>24     got programs in place to keep this closed</p>	<p style="text-align: right;">Page 432</p> <p>1     BY MR. BUCHANAN:</p> <p>2         Q.   We could agree, ma'am, that from</p> <p>3     the perspective of maintaining a closed system</p> <p>4     and having effective controls against diversion,</p> <p>5     it's not appropriate to sell drug to people that</p> <p>6     don't have suspicious order monitoring in place,</p> <p>7     right?</p> <p>8         MS. VANNI: Object to form.</p> <p>9         THE WITNESS: To have controls in</p> <p>10        place to make sure it doesn't go out the</p> <p>11        door --</p> <p>12    BY MR. BUCHANAN:</p> <p>13        Q.   Right.</p> <p>14        A.   -- to illegitimate channels.</p> <p>15        Q.   And what you were asking for were</p> <p>16     their SOM programs, correct?</p> <p>17        A.   Yes.</p> <p>18        Q.   That's what you asked for as part</p> <p>19     of your due diligence information in October of</p> <p>20     2013, right?</p> <p>21        A.   Correct.</p> <p>22        Q.   And if the company was shipping</p> <p>23     drug to people who didn't have programs in</p> <p>24     place, that would be improper, right?</p>
<p style="text-align: right;">Page 431</p> <p>1     system, right?</p> <p>2         A.   I mean, you're making the</p> <p>3     assumption that they were a customer when the</p> <p>4     letter originally went out too. I don't even</p> <p>5     know that.</p> <p>6         Q.   That's a discernable fact, and we</p> <p>7     don't have time to root through the documents</p> <p>8     with you today, but that can be determined.</p> <p>9         A.   Right.</p> <p>10        Q.   I'll represent to you I -- I</p> <p>11     won't make a representation. I'll do that at</p> <p>12     another time.</p> <p>13        But this is a year after your</p> <p>14     letter went out, right?</p> <p>15        A.   Yes. And it's an ongoing thing,</p> <p>16     and the letter might not have gone to the right</p> <p>17     person in the company to start with either. It</p> <p>18     might have had to have gone through, you know,</p> <p>19     several people once it got there, so a lot of</p> <p>20     logistics in the process.</p> <p>21        MR. BUCHANAN: Can I have 1145.</p> <p>22        (Document marked for</p> <p>23        identification as Par-Norton Deposition</p> <p>24        Exhibit No. 22.)</p>	<p style="text-align: right;">Page 433</p> <p>1     MS. VANNI: Objection.</p> <p>2     MR. LEEDER: Objection.</p> <p>3     THE WITNESS: Depending on what</p> <p>4     else they had in place.</p> <p>5    BY MR. BUCHANAN:</p> <p>6        Q.   If they didn't have programs in</p> <p>7     place to ensure the effective control against</p> <p>8     diversion, it would be improper for you to be</p> <p>9     selling to them, right?</p> <p>10       MS. VANNI: Objection.</p> <p>11       THE WITNESS: If it's -- they</p> <p>12     don't have to have something they call</p> <p>13     SOMS, so they have to have appropriate</p> <p>14     controls, yes.</p> <p>15    BY MR. BUCHANAN:</p> <p>16        Q.   Okay. I mean, they certainly</p> <p>17     can't -- well, let's take a look at some.</p> <p>18        Did you form a SOMS advisory team</p> <p>19     in late 2013, early 2014?</p> <p>20        A.   Yes, we did.</p> <p>21        Q.   Mr. Brantley was a member of</p> <p>22     that?</p> <p>23        A.   Yes, he was.</p> <p>24        Q.   Were you a member of that?</p>

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<p style="text-align: right;">Page 434</p> <p>1 A. I think I was a member when Eric</p> <p>2 wasn't there, I believe. I'm not sure if I was</p> <p>3 actually on it or I stepped in when he wasn't</p> <p>4 there.</p> <p>5 Q. So one of the things that started</p> <p>6 to happen after this is you got those resources</p> <p>7 provisioned internally within Qualitest right?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. You had a SOMS compliance</p> <p>12 manager, right, Mr. Brantley?</p> <p>13 A. Yes.</p> <p>14 Q. Went out and started visiting</p> <p>15 customers, right?</p> <p>16 A. Yes.</p> <p>17 Q. And one of the things, lo and</p> <p>18 behold, you started to figure out when you</p> <p>19 started to look at the information in due</p> <p>20 diligence is that some of these customers are</p> <p>21 really doing some fishy stuff, right?</p> <p>22 MS. VANNI: Objection.</p> <p>23 THE WITNESS: I'm sure there are</p> <p>24 customers that we had concerns with,</p>	<p style="text-align: right;">Page 436</p> <p>1 questionnaire was that 30% of the prescriptions</p> <p>2 were for controlled substances, right?</p> <p>3 A. Yes.</p> <p>4 Q. But also you got dispensing</p> <p>5 history, right?</p> <p>6 A. Yes.</p> <p>7 Q. Do you recall our discussion, it</p> <p>8 was probably in the first hour this morning,</p> <p>9 about whether you got dispensing histories from</p> <p>10 customers?</p> <p>11 A. Yes, I do.</p> <p>12 Q. Does this refresh your</p> <p>13 recollection as part of the due diligence when</p> <p>14 you actually started to look into your customers</p> <p>15 that you did get dispensing histories?</p> <p>16 A. He's calling it dispensing</p> <p>17 history. I don't recall the level of detail</p> <p>18 around it, but, yes, that's what's mentioned</p> <p>19 here.</p> <p>20 Q. Okay. And, in fact, and the [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 DEA told you was an average in the country,</p> <p>23 right?</p> <p>24 MS. KOSKI: Objection.</p>
<p style="text-align: right;">Page 435</p> <p>1 sure.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. And so this is a report of</p> <p>4 November 25, 2013 by Mr. Brantley concerning the</p> <p>5 Artemis Pharmacy in Houston, Texas right?</p> <p>6 A. Yes.</p> <p>7 Q. According to the questionnaire it</p> <p>8 says in the middle paragraph, we're just going</p> <p>9 to have to move through it quickly, "According</p> <p>10 to the questionnaire, Artemis Pharmacy fills 600</p> <p>11 prescriptions monthly, with [REDACTED] of the</p> <p>12 prescriptions filled for controlled substances,"</p> <p>13 right?</p> <p>14 A. Yes.</p> <p>15 Q. Do you see that?</p> <p>16 A. I do.</p> <p>17 Q. And, I mean, that's what they --</p> <p>18 you sent out a questionnaire to customers in or</p> <p>19 around October 2013, correct?</p> <p>20 A. Yes.</p> <p>21 Q. And they provided information</p> <p>22 back to you in the questionnaire, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And so what they told you in the</p>	<p style="text-align: right;">Page 437</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. 13% to 15% I think they said,</p> <p>3 right?</p> <p>4 A. It was a guide, yes.</p> <p>5 Q. Right, and so they answered the</p> <p>6 questionnaire and said [REDACTED] right?</p> <p>7 A. Correct.</p> <p>8 Q. And when you actually got the</p> <p>9 dispensing history, lo and behold, it was what?</p> <p>10 A. [REDACTED]</p> <p>11 Q. [REDACTED]</p> <p>12 A. I'm sure most of the dispensing</p> <p>13 history was for a snapshot of time. It looks</p> <p>14 like this is 12 months.</p> <p>15 Q. Yeah, so a 12-month dispensing</p> <p>16 history, correct?</p> <p>17 A. Yes.</p> <p>18 Q. [REDACTED] controlled substances, right?</p> <p>19 A. Yes.</p> <p>20 Q. Again, we got a bunch of that</p> <p>21 hydrocodone in there, and we've talked about the</p> <p>22 billions of pills that y'all were making during</p> <p>23 this period of time, right?</p> <p>24 MS. VANNI: Objection.</p>

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<p style="text-align: right;">Page 438</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Okay. And then there's that</p> <p>4 other drug you mentioned carisoprodol?</p> <p>5 A. Carisoprodol.</p> <p>6 Q. Thank you. You got two of the</p> <p>7 Holy Trinity in the mix, right?</p> <p>8 MS. VANNI: Objection.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Okay. Drugs of abuse, right?</p> <p>12 MS. VANNI: Objection.</p> <p>13 THE WITNESS: Drugs that have a</p> <p>14 legitimate use.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. And then "According to the</p> <p>17 questionnaire, [REDACTED] of all prescriptions were</p> <p>18 paid in cash," right?</p> <p>19 A. Yes.</p> <p>20 Q. Another red flag, right?</p> <p>21 MS. VANNI: Objection.</p> <p>22 THE WITNESS: Depending on the</p> <p>23 business type, yes.</p> <p>24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 440</p> <p>1 and seen this is a place where people are going</p> <p>2 in, whipping out wads of cash and getting drugs?</p> <p>3 MS. VANNI: Objection.</p> <p>4 THE WITNESS: You couldn't have</p> <p>5 -- you couldn't have determined that</p> <p>6 just by walking in.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. Well, you could have sat there</p> <p>9 and seen people pulling cash out of their</p> <p>10 pocket, no front-end merchandise, right?</p> <p>11 MS. VANNI: Objection.</p> <p>12 THE WITNESS: You're not really</p> <p>13 going to go and like just stand there</p> <p>14 and watch people pay for their</p> <p>15 prescriptions all day. Photographs</p> <p>16 would have told, did tell, obviously,</p> <p>17 that they had very little front-end</p> <p>18 merchandise. Any one of those things is</p> <p>19 not the be all to end all. It's the</p> <p>20 combination of things in this case.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Okay. And, certainly, as part of</p> <p>23 this process, I mean, you didn't even need to</p> <p>24 look at chargeback data. I mean, frankly, you</p>
<p style="text-align: right;">Page 439</p> <p>1 Q. And so this is the type of</p> <p>2 information the company was getting when it</p> <p>3 started to do the due diligence and it had the</p> <p>4 resources that it applied to it in 2013, right?</p> <p>5 A. Yes.</p> <p>6 Q. And the recommendation of</p> <p>7 Mr. Brantley was?</p> <p>8 A. To discontinue shipments.</p> <p>9 Q. Stop selling, right?</p> <p>10 A. Yes.</p> <p>11 Q. Right.</p> <p>12 This one presented unreasonable</p> <p>13 risk of diversion, right?</p> <p>14 A. It presented issues with the</p> <p>15 volumes, the percentages of controlled to</p> <p>16 noncontrolled and the cash, so items of concern,</p> <p>17 definitely.</p> <p>18 Q. Okay. Did they have front-end</p> <p>19 merchandise?</p> <p>20 A. According to this, no, they did</p> <p>21 not.</p> <p>22 Q. Okay. So that means you didn't</p> <p>23 even need to ask for the information from them,</p> <p>24 you could have just gone down there, walked in</p>	<p style="text-align: right;">Page 441</p> <p>1 sent -- you requested a dispensing history, you</p> <p>2 got it. You sent a questionnaire, you got it.</p> <p>3 Mr. Brantley made the assessment, this is a</p> <p>4 problem, no more business, boom?</p> <p>5 A. In this particular case.</p> <p>6 MS. VANNI: Objection.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. Yeah, and there's several that</p> <p>10 when you actually put boots on the ground and</p> <p>11 you actually looked at who you were selling</p> <p>12 drugs to were problem customers, right?</p> <p>13 MS. VANNI: Objection.</p> <p>14 THE WITNESS: Possibly, yes.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. And let's not make this</p> <p>17 challenging. We agree, don't we, ma'am, that</p> <p>18 that is an important thing to do?</p> <p>19 MS. VANNI: Objection.</p> <p>20 THE WITNESS: To visit your</p> <p>21 customers?</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. Yes.</p> <p>24 A. It's a good addition to a DEA to</p>

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<p style="text-align: right;">Page 442</p> <p>1 the DEA required SOM program, yes.</p> <p>2 Q. Okay. And, I mean, you learned</p> <p>3 that, frankly, you're doing business with people</p> <p>4 you really shouldn't be, right?</p> <p>5 MS. VANNI: Objection.</p> <p>6 THE WITNESS: We learned that</p> <p>7 there's customers that we don't want to</p> <p>8 do business with.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. You learned there were customers</p> <p>11 in October of 2013 that when you asked for their</p> <p>12 SOM program they said what's that?</p> <p>13 MS. VANNI: Objection.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Right? Do you remember that?</p> <p>16 A. There were probably some, yes.</p> <p>17 And a lot of customers didn't refer to it as SOM</p> <p>18 either. You know, the DEA regulation doesn't</p> <p>19 call it a SOM either, so that's -- that part is</p> <p>20 understandable.</p> <p>21 Q. But let's be clear, every</p> <p>22 customer who you would be dealing with all the</p> <p>23 way down to the pharmacy level, okay, they've</p> <p>24 got to register with the DEA right?</p>	<p style="text-align: right;">Page 444</p> <p>1 familiar, but I don't remember the</p> <p>2 interaction.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. Do you remember having problems</p> <p>5 for a long time getting evidence they even had a</p> <p>6 SOM program or something that served that</p> <p>7 purpose?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: I don't remember</p> <p>10 customer specific. If you have</p> <p>11 information.</p> <p>12 (Document marked for</p> <p>13 identification as Par-Norton Deposition</p> <p>14 Exhibit No. 23.)</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Passing you what we're marking</p> <p>17 Exhibit 23.</p> <p>18 FW Kerr is a distributor, right?</p> <p>19 A. I believe they are. I'm not</p> <p>20 positive, but I think they are.</p> <p>21 MS. VANNI: It's 24.</p> <p>22 THE WITNESS: Should be 24.</p> <p>23 MR. BUCHANAN: Which number is</p> <p>24 that one?</p>
<p style="text-align: right;">Page 443</p> <p>1 A. Yes, they do.</p> <p>2 Q. Okay. They've got to make the</p> <p>3 same promise you're making, right?</p> <p>4 A. Yes.</p> <p>5 Q. To maintain effective controls</p> <p>6 against diversion, right?</p> <p>7 A. Correct.</p> <p>8 Q. To have a suspicious order</p> <p>9 monitoring program, right?</p> <p>10 MS. VANNI: Objection.</p> <p>11 THE WITNESS: Yes. To have</p> <p>12 controls in place.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. Right. Okay.</p> <p>15 I would love to go through a few</p> <p>16 more of these. I'm being told that I am clock</p> <p>17 limited.</p> <p>18 MR. BUCHANAN: Can I have 1101,</p> <p>19 please.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Do you remember the interaction</p> <p>22 you all had with FW Kerr?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 THE WITNESS: The name is</p>	<p style="text-align: right;">Page 445</p> <p>1 THE WITNESS: This is 22, 21.</p> <p>2 MR. BUCHANAN: What that means is</p> <p>3 that --</p> <p>4 THE WITNESS: This is 23 that you</p> <p>5 just handed me.</p> <p>6 MS. REESE: You gave us 23.</p> <p>7 We're up to 24.</p> <p>8 MR. BUCHANAN: We are up to 24,</p> <p>9 okay. I'll trust everyone else is</p> <p>10 paying better attention than me. Thank</p> <p>11 you. For posterity, we're marking this</p> <p>12 as 24, and I shouldn't say -- for all</p> <p>13 purposes this is 24.</p> <p>14 (Document marked for</p> <p>15 identification as Par-Norton Deposition</p> <p>16 Exhibit No. 24.)</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Passing you Exhibit 24, ma'am,</p> <p>19 this is an interaction your team, Mr. Brantley</p> <p>20 had with Mr. Young from FW Kerr in November 21</p> <p>21 or in November 2014.</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And there's further back</p>

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<p style="text-align: right;">Page 446</p> <p>1 and forth with FW Kerr trying to find some SOMS,  2 to see if they've got anything, they're doing  3 anything.  4 Do you recall getting some  5 pressure from the sales department about cutting  6 FW Kerr because they didn't have a SOMS program?  7 MS. VANNI: Objection.  8 THE WITNESS: I do not recall  9 that.  10 BY MR. BUCHANAN:  11 Q. That would not be appropriate,  12 would it, ma'am?  13 MS. VANNI: Objection.  14 BY MR. BUCHANAN:  15 Q. For the sales department to  16 interfere with the compliance function out of  17 concern for sales?  18 MS. VANNI: Objection.  19 THE WITNESS: The sales  20 department would, would push back if  21 we're looking to take action against a  22 customer from a compliance perspective.  23 If they didn't, they wouldn't be sales  24 at any company, I would expect that, but</p>	<p style="text-align: right;">Page 448</p> <p>1 established after the -- in this 2013 timeline,  2 correct?  3 A. That was when we implemented the  4 changes, the modifications.  5 Q. And we looked at a PowerPoint, I  6 think, from the first quarter of 2013 where you  7 were going to bring that program into your  8 group.  9 Do you remember that?  10 A. Yes.  11 Q. Does that help firm up the time?  12 A. Yes.  13 Q. So FW Kerr is getting a letter  14 from Mr. Brantley, head of SOM compliance,  15 right?  16 A. Yes.  17 Q. Does this refresh your  18 recollection, ma'am, that during the time there,  19 the company, in fact, did utilize chargeback  20 data as part of identifying secondary customers  21 that were problematic?  22 A. I think this was after I left.  23 MS. VANNI: I would note that the  24 -- she is not a recipient of this</p>
<p style="text-align: right;">Page 447</p> <p>1 the -- any time that we had that,  2 usually once we gave them the  3 information, they came around.  4 BY MR. BUCHANAN:  5 Q. Okay. Well, let's be clear just,  6 so we take a step back.  7 Maintenance of the closed system  8 of distribution for controlled substances should  9 be maintained at all costs, right?  10 MS. VANNI: Objection.  11 THE WITNESS: It should be  12 maintained.  13 BY MR. BUCHANAN:  14 Q. And it shouldn't yield to sales  15 concerns, right?  16 MS. VANNI: Objection.  17 THE WITNESS: Sales, once we took  18 over the controlled substance monitoring  19 program, sales would not be the  20 decision-maker.  21 BY MR. BUCHANAN:  22 Q. Okay. The time when you took  23 over the controlled substance monitoring program  24 or the SOMS for Qualitest that was in -- we</p>	<p style="text-align: right;">Page 449</p> <p>1 e-mail.  2 THE WITNESS: December.  3 BY MR. BUCHANAN:  4 Q. Okay. Well, let's reorient  5 ourselves to what's happening here.  6 Mr. Young of Frank Kerr is  7 getting a letter from Mr. Brantley of Qualitest,  8 your report, correct?  9 A. Yes.  10 Q. Okay. In the middle it says, "On  11 March 18, 2014, you were sent a list of  12 customers identified while reviewing chargeback  13 data and asked for due diligence information for  14 these customers."  15 Do you see that?  16 A. I do.  17 Q. "To date we have not received a  18 response from you."  19 Do you see that?  20 A. Yes.  21 Q. And so that would be, you know,  22 seven months later? Do I have the timing right,  23 March to November, that's about seven months?  24 A. Yes.</p>



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<p style="text-align: right;">Page 450</p> <p>1 Q. Okay. So you send your initial</p> <p>2 customer letter in October of 2013 saying we</p> <p>3 need information on you.</p> <p>4 And then as part of your SOMS</p> <p>5 process here in 2014, the company is looking at</p> <p>6 chargeback data, correct?</p> <p>7 MS. VANNI: Object to form.</p> <p>8 THE WITNESS: It says that.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Well, Mr. Brantley is in an</p> <p>11 outside correspondence with the distributor</p> <p>12 saying we've looked at the due diligence</p> <p>13 information you gave us, we've looked at</p> <p>14 chargeback data, correct?</p> <p>15 A. That's what he is saying, yes.</p> <p>16 Q. Right. And he's saying he has</p> <p>17 identified a number of customers of concern,</p> <p>18 right?</p> <p>19 A. For Frank Kerr, yes.</p> <p>20 Q. Okay. "To date we have not</p> <p>21 received a response from you," correct?</p> <p>22 A. Yes.</p> <p>23 Q. And what Mr. Brantley is now</p> <p>24 telling him six months after he hasn't gotten a</p>	<p style="text-align: right;">Page 452</p> <p>1 customers as evidenced in this exhibit, correct?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: That's what it</p> <p>4 says, yes.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. And what's happening here is</p> <p>7 you're cutting them off because you're dealing</p> <p>8 with people who you have no evidence they've got</p> <p>9 a proper medical purpose that are buying from FW</p> <p>10 Kerr, right?</p> <p>11 A. I don't think we have no medical</p> <p>12 -- no proof of medical evidence. We have</p> <p>13 concerns about the quantities that they were</p> <p>14 buying or that they were shipping to these</p> <p>15 customers.</p> <p>16 Q. Right.</p> <p>17 A. And what we would have done is</p> <p>18 told Frank Kerr to do research on these</p> <p>19 customers. We want to know if you've visited</p> <p>20 them or done research.</p> <p>21 Q. Right. So, in other words, the</p> <p>22 measures that were implemented as part of the</p> <p>23 revamped SOM program in late 2013 and now into</p> <p>24 2014 included looking at chargeback data, and we</p>
<p style="text-align: right;">Page 451</p> <p>1 response, given the absence of a response from</p> <p>2 you, we're asking you to immediately cease</p> <p>3 distribution in selling Qualitest hydrocodone to</p> <p>4 those people, right?</p> <p>5 A. Yes.</p> <p>6 Q. Those companies, right?</p> <p>7 A. Mm-hmm.</p> <p>8 Q. Okay. Because continued sales</p> <p>9 represent what, an undue risk?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. In addition, you're</p> <p>12 reducing what you're willing to sell to that</p> <p>13 customer, right?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. So what we see here is in</p> <p>16 2014 we see as a result of some of the</p> <p>17 individual boots on the ground going to</p> <p>18 pharmacies and collecting due diligence on them,</p> <p>19 identifying problematic customers and cutting</p> <p>20 them off, right?</p> <p>21 A. Yes.</p> <p>22 Q. We also see that when you look at</p> <p>23 customers of customer data through chargeback</p> <p>24 data that you can identify problematic secondary</p>	<p style="text-align: right;">Page 453</p> <p>1 saw that was one of the phases in your</p> <p>2 multi-phased approach to revamping the system,</p> <p>3 right?</p> <p>4 A. Yes.</p> <p>5 Q. And looking at chargeback data</p> <p>6 and what it could reveal was customers of</p> <p>7 customer's utilization of or acquisition of</p> <p>8 Qualitest product, right?</p> <p>9 A. Yes.</p> <p>10 Q. And so from that chargeback data,</p> <p>11 these eight pharmacies were identified as</p> <p>12 customers of interest, given the size and the</p> <p>13 order nature, correct?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: Customers of</p> <p>16 interest, yes.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. And you asked for more</p> <p>19 information from your direct customer, didn't</p> <p>20 receive it in April, right?</p> <p>21 A. Right.</p> <p>22 Q. Didn't receive it in May, didn't</p> <p>23 receive it for six months, right?</p> <p>24 A. That wouldn't be unusual from the</p>

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<p style="text-align: right;">Page 454</p> <p>1 aspect of if you're asking that customer to give</p> <p>2 you data on all of these customers, if they</p> <p>3 haven't visited all of them, they're going to</p> <p>4 need time to set those visits up and to do their</p> <p>5 due diligence.</p> <p>6 Q. I understand.</p> <p>7 But from the time you sent your</p> <p>8 letter, your letter --</p> <p>9 A. Yes.</p> <p>10 Q. -- from October 18 of 2013 to the</p> <p>11 time of these customers and the quotas being</p> <p>12 reduced to this particular distributor, FW Kerr,</p> <p>13 it's about a year or more, right, 13 months?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And we can agree that this</p> <p>16 letter reflects that the way in which these</p> <p>17 customers of your customer FW Kerr were</p> <p>18 identified, as reflected in this letter, is</p> <p>19 through the use of chargeback data, correct?</p> <p>20 MS. VANNI: Object to the form.</p> <p>21 THE WITNESS: That's what it</p> <p>22 says, but I don't recall us using the</p> <p>23 chargeback data during my time with</p> <p>24 Qualitest. We tried, we tried to use</p>	<p style="text-align: right;">Page 456</p> <p>1 Q. Okay. I have one last area,</p> <p>2 please, counsel, if you'll indulge me a few</p> <p>3 minutes. Do you need a moment? Because we're</p> <p>4 going to have change the hot seat in a second on</p> <p>5 my side.</p> <p>6 A. We're good.</p> <p>7 Q. I see from your CV that you were</p> <p>8 a member of a number of industry groups; is that</p> <p>9 fair?</p> <p>10 A. Yes.</p> <p>11 MR. BUCHANAN: Could we go off</p> <p>12 the record.</p> <p>13 THE VIDEOGRAPHER: Going off the</p> <p>14 record, the time is 4:33 p.m.</p> <p>15 (Pause.)</p> <p>16 THE VIDEOGRAPHER: Back on the</p> <p>17 record, 4:35 p.m.</p> <p>18 MR. BUCHANAN: Okay. Let's see</p> <p>19 if we can bring this in for a landing,</p> <p>20 with me.</p> <p>21 (Document marked for</p> <p>22 identification as Par-Norton Deposition</p> <p>23 Exhibit No. 25.)</p> <p>24 BY MR. BUCHANAN:</p>
<p style="text-align: right;">Page 455</p> <p>1 it, but the data that we were getting</p> <p>2 was not -- it didn't show us anything we</p> <p>3 needed to, so that's why I'm surprised</p> <p>4 to see chargeback data.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. And I'll represent to you, ma'am,</p> <p>7 that we have letters for other distributors who</p> <p>8 the company was dealing with identifying</p> <p>9 problematic customers identified through</p> <p>10 chargeback data?</p> <p>11 A. Okay.</p> <p>12 Q. I mean, you're not -- you don't</p> <p>13 have any evidence, sitting here today, to</p> <p>14 dispute Mr. Brantley's letters that he says he</p> <p>15 used chargeback data, right?</p> <p>16 MS. VANNI: Object to form.</p> <p>17 THE WITNESS: No, I do not.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Okay. And we can agree the</p> <p>20 letter actually reflects that they used</p> <p>21 chargeback data or that Qualitest used</p> <p>22 chargeback data to identify problematic</p> <p>23 secondary customers, true?</p> <p>24 A. That's what it says, yes.</p>	<p style="text-align: right;">Page 457</p> <p>1 Q. Passing you what we're marking as</p> <p>2 Exhibit 25, I think we're back on track with the</p> <p>3 exhibit numbers. Copies for counsel, please.</p> <p>4 MR. BUCHANAN: Can we pull up</p> <p>5 E630, please, Bradley. Thank you.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. I saw in your resume, ma'am, I</p> <p>8 don't think we have time to pull it back up, but</p> <p>9 you list in your resume old one, new one,</p> <p>10 various forms your involvement and engagement</p> <p>11 with various industry working groups, right?</p> <p>12 A. Correct.</p> <p>13 Q. These are the minutes from an</p> <p>14 industry working group, anti-diversion working</p> <p>15 group meeting from 2013.</p> <p>16 Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Okay. Something you sent around</p> <p>19 after I guess you went to the meeting to</p> <p>20 Mr. Brantley?</p> <p>21 A. Yes.</p> <p>22 Q. This is October 11, 2013. Can</p> <p>23 you -- there we go.</p> <p>24 MR. BUCHANAN: Thank you,</p>

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<p style="text-align: right;">Page 458</p> <p>1 Bradley.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. And then you've got your DEA</p> <p>4 compliance trip report, right?</p> <p>5 A. Yes.</p> <p>6 Q. Did you put this together?</p> <p>7 A. Yes, I did.</p> <p>8 Q. And it accurately reflected what</p> <p>9 happened, as best you were able to determine?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And so this is a meeting</p> <p>12 of the Anti-Diversion Industry Working Group</p> <p>13 held in Chicago, right?</p> <p>14 A. Correct.</p> <p>15 Q. And you've got -- you've got some</p> <p>16 folks from manufacturers, Mallinckrodt, right?</p> <p>17 A. Yes.</p> <p>18 Q. You've got HD Smith and</p> <p>19 AmerisourceBergen, right?</p> <p>20 A. Yes.</p> <p>21 Q. McKesson dialing in, right?</p> <p>22 A. Yes.</p> <p>23 Q. AmerisourceBergen there in</p> <p>24 person?</p>	<p style="text-align: right;">Page 460</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Okay. And so Anti-Diversion</p> <p>3 Industry Working Group, that was a group of</p> <p>4 industry participants that came together from</p> <p>5 time to time, right?</p> <p>6 A. Not -- we really didn't meet a</p> <p>7 lot. It was more for one purpose.</p> <p>8 Q. Okay. And this notes it's the</p> <p>9 second meeting of the group, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And then you had some</p> <p>12 folks from Quarles &amp; Brady, those are lawyers?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. So you had lawyers, you</p> <p>15 had distributors, you had manufacturers all kind</p> <p>16 of in this group together, right?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 THE WITNESS: Correct.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. All right. And then maybe we'll</p> <p>21 have time to call out some of these. Carmen is</p> <p>22 a person who spoke that day. You see at the</p> <p>23 bottom of the first page, Carmen Catizone?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 459</p> <p>1 MR. SCHACK: Objection. What are</p> <p>2 you looking at? Sorry, I don't have it.</p> <p>3 MR. BUCHANAN: Can we get the</p> <p>4 630.2.</p> <p>5 MS. KOSKI: It took our screen</p> <p>6 away too.</p> <p>7 MR. SCHACK: Yeah, I can't see</p> <p>8 the --</p> <p>9 MR. BUCHANAN: Just turn the one</p> <p>10 right there. Okay. I can't solve for</p> <p>11 that, I'm sorry. 630.2.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. At the top we have a list of</p> <p>14 attendees at the meeting, and you were the</p> <p>15 Qualitest attendee, correct?</p> <p>16 A. Yes, I was.</p> <p>17 MR. BUCHANAN: Does everybody</p> <p>18 have a way to get an angle on this right</p> <p>19 now? If someone needs to stand up over</p> <p>20 my shoulder, they're welcome to do that.</p> <p>21 MR. SCHACK: What exhibit number,</p> <p>22 Exhibit 25?</p> <p>23 MR. BUCHANAN: Yeah.</p> <p>24 MR. SCHACK: All right.</p>	<p style="text-align: right;">Page 461</p> <p>1 Q. And she gave some background on</p> <p>2 NAPB, right?</p> <p>3 A. He. He was the executive</p> <p>4 director of NAPB.</p> <p>5 Q. NAPB is what?</p> <p>6 A. National Association of Boards of</p> <p>7 Pharmacy.</p> <p>8 Q. Okay. And Carmen is providing</p> <p>9 information on wholesalers or secondary</p> <p>10 wholesalers being a diversion risk, correct?</p> <p>11 A. Second -- that's what he's</p> <p>12 saying, yes.</p> <p>13 Q. I'm sorry. It's the last</p> <p>14 paragraph.</p> <p>15 A. Yes, that's what he's saying.</p> <p>16 Q. First page. Okay.</p> <p>17 And then there's some member</p> <p>18 presentations that occur?</p> <p>19 A. Yes.</p> <p>20 Q. Right. And the members would be</p> <p>21 all these folks that are identified other than</p> <p>22 the outside speakers, right?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And one of the team</p>

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<p style="text-align: right;">Page 462</p> <p>1 members, and you don't identify that person, is</p> <p>2 that just some code of conduct or something when</p> <p>3 you go to these meetings, you're not allowed to</p> <p>4 say who said what?</p> <p>5 MS. VANNI: Object to form.</p> <p>6 THE WITNESS: No.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. I don't know, you didn't?</p> <p>9 A. No, it was just one of the team</p> <p>10 members. I don't recall which one it was, but</p> <p>11 one of them presented IMS data.</p> <p>12 Q. Okay. Well, for the outside</p> <p>13 presenter, you identify them by name and then</p> <p>14 for the other people you attribute them as team</p> <p>15 members, right?</p> <p>16 MR. SCHACK: Object to form.</p> <p>17 THE WITNESS: No reason.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Okay. "Member Presentation</p> <p>20 (Based on IMS data). One of the team members</p> <p>21 has purchased the upgraded IMS subscription and</p> <p>22 using the data IMS provides, presented a heat</p> <p>23 map of the US showing the top prescribers for</p> <p>24 oxycodone and hydrocodone from 2010 - 2013,"</p>	<p style="text-align: right;">Page 464</p> <p>1 you know, there's this IMS data with a heat map?</p> <p>2 A. I did. It's not standard</p> <p>3 information to get. It's extremely, extremely</p> <p>4 costly, in the millions, from what I was told to</p> <p>5 get that information. So it wasn't something</p> <p>6 that we wanted to do at that time. It gave us</p> <p>7 some information, but DEA was presenting similar</p> <p>8 things at conferences, so it wasn't something</p> <p>9 that we pursued.</p> <p>10 Q. Okay. Well, I mean, you could</p> <p>11 drill down, right, using these heat maps?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: I don't know if we</p> <p>14 could in this case or not. The</p> <p>15 presentation wasn't -- it wasn't --</p> <p>16 like, it wasn't -- they didn't spend a</p> <p>17 long time on it. It was just here's</p> <p>18 something out there. The whole purpose</p> <p>19 of the group was to try to do anything</p> <p>20 that we could to help with the abuse and</p> <p>21 diversion, and so this was presented as</p> <p>22 a tool that one company had that -- just</p> <p>23 to educate people that it was out there</p> <p>24 on the team.</p>
<p style="text-align: right;">Page 463</p> <p>1 right?</p> <p>2 A. Yes.</p> <p>3 Q. And it showed the following</p> <p>4 states in this heat map.</p> <p>5 You see this?</p> <p>6 A. I do.</p> <p>7 Q. Yeah, and you identify several --</p> <p>8 for hydrocodone you've got Ohio, California,</p> <p>9 Texas, you see Florida in there, other states in</p> <p>10 the mix, right?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. You've got them also for</p> <p>13 the seven and a half milligrams hydrocodone,</p> <p>14 also for 10 milligrams, correct?</p> <p>15 A. Yes.</p> <p>16 Q. All right. And so these are</p> <p>17 states that are popping up on this heat map,</p> <p>18 right?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: That's what it was</p> <p>21 showing, yes.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. Okay. Did you go back to the</p> <p>24 company after you went to this and said, hey,</p>	<p style="text-align: right;">Page 465</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. All right. I mean, what they</p> <p>3 said you could see was you could see a map of</p> <p>4 the US showing the top prescribers for oxycodone</p> <p>5 and hydrocodone, right? That's what it showed,</p> <p>6 the heat map?</p> <p>7 A. I don't know if it drilled down</p> <p>8 to the actual names of prescribers or anything</p> <p>9 like that.</p> <p>10 Q. Well, you were sufficiently</p> <p>11 impressed, you say --</p> <p>12 A. I was.</p> <p>13 MS. VANNI: Object to form.</p> <p>14 THE WITNESS: I was. It was</p> <p>15 interesting information.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Not only interesting, you said we</p> <p>18 need to get it?</p> <p>19 A. I wanted to get it if it was</p> <p>20 reasonable and was something that we could use</p> <p>21 on a regular basis, yeah.</p> <p>22 Q. Well, in the context of billions</p> <p>23 and billions of pills that you're selling and</p> <p>24 the tens of thousands of people that are</p>

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<p style="text-align: right;">Page 466</p> <p>1 overdosing each year, I mean, how many millions 2 of dollars is too much to spend to acquire data 3 to help prevent diversion? 4 A. I don't think -- 5 MS. VANNI: Objection, form. 6 THE WITNESS: I don't think that 7 this data would have been -- it was 8 informative more than it was helpful in 9 preventing diversion. 10 BY MR. BUCHANAN: 11 Q. What you wrote here was that "we 12 need to obtain this data"? 13 A. That's what I wanted to do, yes. 14 Q. This was as of -- 15 A. Because I always want to improve 16 upon our compliance and the tools that are 17 available to us and to what we're doing. 18 Q. Okay. Do you remember how much 19 it was? I would like to know how much -- 20 A. I don't remember. 21 Q. -- was too much for Qualitest? 22 A. I don't remember, to be honest. 23 MS. VANNI: Objection. 24 THE WITNESS: I don't remember.</p>	<p style="text-align: right;">Page 468</p> <p>1 get information that could be relevant to you, 2 in your view? 3 MS. VANNI: Object to form. 4 BY MR. BUCHANAN: 5 Q. As part of your role and 6 function? 7 A. I don't know if it was really 8 anything new compared to what DEA was putting 9 out there. Again, at that point I hadn't 10 attended it, so it's probably more helpful to a 11 wholesaler, HDMA. 12 Q. Okay. I was more generalizing. 13 I mean, this particular working group, I mean, 14 getting together with others in the industry, 15 collaborating, understanding what's happening, 16 data sources that might be available, that was 17 information that you brought back to incorporate 18 in your practice? 19 MS. VANNI: Object to form. 20 THE WITNESS: It was information 21 that I brought back and made the team 22 knowledgeable of, and, ultimately, the 23 goal and the end result of this team was 24 the red flags video that NABP still</p>
<p style="text-align: right;">Page 467</p> <p>1 BY MR. BUCHANAN: 2 Q. Okay. And then there's some 3 discussion on other key topics, how to best 4 assure success of the team partnering with the 5 DEA. 6 Do you see that? It's the first 7 bullet under "Other Key Topics Discussed." 8 A. Yes, how best to assure the 9 success in partnering to fight drug diversion. 10 Q. Right. And so the "team felt we 11 should evaluate the HDMA's actions." 12 Do you see that? 13 A. Yes, I do. 14 Q. Okay. And who is the HDMA? 15 A. Healthcare Distributor Management 16 Association. 17 Q. And were those meetings that you 18 also attended? 19 A. They had a conference once a 20 year. I attended one, but at this point I had 21 not -- I have attended one in the past, but at 22 this point I had never attended any. 23 Q. Okay. And so you'd go to these 24 meetings and as part of these meetings, you'd</p>	<p style="text-align: right;">Page 469</p> <p>1 today has on their website. 2 BY MR. BUCHANAN: 3 Q. The red flags video being signs 4 for pharmacies, signs for pharmacists, et 5 cetera? 6 A. Signs for -- yes, it was 7 educational for pharmacists to show them some of 8 the things to look for that we thought would be 9 helpful. 10 Q. How about a video for any of your 11 customers, your distributors, one that would 12 show them, hey, these are what problematic 13 pharmacies look like and lines out the door and 14 red flags and other things that would help them? 15 MS. VANNI: Objection. 16 THE WITNESS: They were, as part 17 of the -- you know, as part of NABP, 18 they would have been seeing that, that 19 video anyway. 20 BY MR. BUCHANAN: 21 Q. Like FW Kerr would have been 22 seeing that? 23 MS. VANNI: Objection. 24 THE WITNESS: They could have.</p>



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<p style="text-align: right;">Page 470</p> <p>1 It's public knowledge. It's publicly on 2 the website today. 3 MR. BUCHANAN: Okay. Can I have 4 1153. 5 (Document marked for 6 identification as Par-Norton Deposition 7 Exhibit No. 26.) 8 BY MR. BUCHANAN: 9 Q. These are minutes of another DEA 10 compliance trip report. This is from the same 11 window of time, fall 2013? 12 A. Mm-hmm. 13 Q. I noticed, just from looking 14 through your file, ma'am, that in this 2013 15 period, you're going to outside industry 16 functions and sending -- and memorializing them 17 in trip reports and sending them out to your 18 team when you get back; is that fair? 19 A. Something that I've always done, 20 not just in 2013. 21 Q. So this is of the New Jersey 22 Pharmaceutical Industry Group meeting from 23 November of 2013, correct? 24 A. Yes.</p>	<p style="text-align: right;">Page 472</p> <p>1 kind of thing, not really a 2 collaboration, not really a 3 collaboration. There wasn't -- there 4 was no direct outcome of this meeting, 5 like the anti-diversion group meetings, 6 and this was actual -- this group was 7 actually started by Gerry McAleer, the 8 local special agent in charge of the DEA 9 office in Newark, New Jersey. 10 BY MR. BUCHANAN: 11 Q. Okay. Is he in attendance at 12 this? 13 A. I don't think he's in attendance 14 at this one. He was in attendance and spoke at 15 the first one -- 16 Q. Okay. So what -- 17 A. -- and he was invited to other 18 meetings. Other members of DEA were invited to 19 meetings afterwards. 20 Q. Well, we could agree he's not at 21 this one, correct? 22 A. I wouldn't know without reading 23 the whole thing, but I don't think so. 24 Q. Okay. Well, certainly, with</p>
<p style="text-align: right;">Page 471</p> <p>1 Q. Hosted at Novartis, correct? 2 A. Yes, this particular one was. 3 Q. It's got a bunch of 4 manufacturers. It's got J&amp;J, it's got Novartis, 5 it's got Purdue. 6 A. Yeah. 7 Q. You're in there, we've got 8 Watson. 9 A. Yes, a lot of attendees. 10 Q. We see distributors there as 11 well, correct? 12 A. Yes. 13 Q. AmerisourceBergen, correct? 14 A. Yes. 15 Q. And so this is another one of 16 those settings where people would all get 17 together, exchange ideas, exchange insights, 18 collaborate? 19 MS. VANNI: Objection. 20 THE WITNESS: This is a 21 different -- different type of meeting 22 than the anti-diversion. This meeting 23 was really bringing people together to 24 share experiences to -- for benchmarking</p>	<p style="text-align: right;">Page 473</p> <p>1 regard to the additional attendees, do you see 2 any notation of a DEA attendee? 3 A. No. 4 Q. Okay. And there's a listing of 5 the general meeting charter, correct? The 6 purpose of the New Jersey Pharmaceutical 7 Industry Group meeting was to discuss education 8 and other industry practices regarding DEA 9 compliance. Let's pause on that for a moment. 10 You were not an attendee at this 11 meeting; is that right? 12 A. I believe I was; otherwise, I 13 wouldn't be doing a trip report on it. 14 Qualitest attendee was Rohit, Rohit Sutaria was 15 my person in Charlotte. It looks like he was 16 the only attendee. 17 Q. Okay. And would you have 18 received compliance trip reports from your team? 19 A. Yes. 20 Q. Okay. 21 A. I would ask -- 22 Q. So you don't doubt that you 23 received this, right? 24 A. No, I don't doubt that.</p>

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<p style="text-align: right;">Page 474</p> <p>1 Q. Sure.</p> <p>2 Next paragraph, "The goal of the</p> <p>3 NJPIG is to increase compliance with DEA</p> <p>4 requirements through the shared knowledge and</p> <p>5 experience of the group members."</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And was that one of -- was</p> <p>9 that something that was happening at these</p> <p>10 meetings; y'all were sharing your experiences</p> <p>11 back and forth?</p> <p>12 A. Yes. I mean, there were some</p> <p>13 members that were more senior, others were newer</p> <p>14 to DEA compliance. There was a fine line</p> <p>15 because there's a lot of things that we couldn't</p> <p>16 speak about from confidentiality perspective,</p> <p>17 because we were also competitors, but there was</p> <p>18 information sharing to the extent that it could</p> <p>19 be.</p> <p>20 Q. Okay. Let's go to 1153.2. It</p> <p>21 talks about 2014 quota letters. Do you see</p> <p>22 that?</p> <p>23 A. Yes.</p> <p>24 Q. And quota letters are the</p>	<p style="text-align: right;">Page 476</p> <p>1 a standard turnaround might be eight to</p> <p>2 ten weeks, and in one instance that I</p> <p>3 can recall it was taking DEA upwards of</p> <p>4 24 weeks to respond to a quota letter,</p> <p>5 which, as you can see from the comment</p> <p>6 there, it had an impact on drug supply</p> <p>7 and created drug shortages.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. Okay. And strategies for dealing</p> <p>10 with them, right?</p> <p>11 A. Not really strategies. I mean --</p> <p>12 MS. VANNI: Objection.</p> <p>13 THE WITNESS: -- there's</p> <p>14 nothing -- not much that companies can</p> <p>15 do. If DEA wants to take longer, they</p> <p>16 take longer, you know.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. Let's then turn to 1153.4, also</p> <p>19 discussing SOM programs, right?</p> <p>20 A. Yes.</p> <p>21 Q. And question being put out to</p> <p>22 everybody at the meeting, "Is anyone auditing</p> <p>23 customers?"</p> <p>24 MS. VANNI: Object to form.</p>
<p style="text-align: right;">Page 475</p> <p>1 manufacturers will send in a request for</p> <p>2 permission to make a certain quantity of</p> <p>3 controlled substance?</p> <p>4 A. Yes, it's based on sales data.</p> <p>5 It's based on IMS data, prescriptions written.</p> <p>6 DEA takes a lot of other factors into</p> <p>7 consideration, meet with FDA, et cetera.</p> <p>8 Q. And members here are expressing</p> <p>9 surprise to receive the quota letter for 2014.</p> <p>10 Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. And some members said it was</p> <p>13 because of the reason that GAO is reviewing last</p> <p>14 two years of quota issued by DEA, right?</p> <p>15 A. Yes, that's what it says.</p> <p>16 Q. Okay. Was one of the things that</p> <p>17 industry would discuss at these meetings what</p> <p>18 participants were doing with regard to their</p> <p>19 quota letters?</p> <p>20 MR. LEEDER: Objection.</p> <p>21 THE WITNESS: They would never</p> <p>22 discuss quota amounts. They would talk</p> <p>23 about the delays in getting responses</p> <p>24 from DEA. So a standard -- for example,</p>	<p style="text-align: right;">Page 477</p> <p>1 THE WITNESS: Correct, because it</p> <p>2 was something that --</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. So just let's pause on that.</p> <p>5 A. Okay.</p> <p>6 Q. I mean, that's what it reflects,</p> <p>7 right, "Is anyone auditing customers?"</p> <p>8 A. Yes.</p> <p>9 Q. Okay. "Computerized statistical</p> <p>10 models?" Right?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And so this was a vehicle,</p> <p>13 this New Jersey Pharmaceutical Industry Group to</p> <p>14 exchange information about what people were</p> <p>15 doing on auditing, what people were doing on</p> <p>16 SOMS, what people were doing with statistical</p> <p>17 models, right?</p> <p>18 A. To a certain extent. So you</p> <p>19 might get an answer to this question like a yes</p> <p>20 or no, but you wouldn't necessarily get a lot of</p> <p>21 detail because that was confidential to the</p> <p>22 company.</p> <p>23 Q. And, right, and we see actually</p> <p>24 some of the manufacturers sharing information by</p>

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<p style="text-align: right;">Page 478</p> <p>1 name as reflected in Rohit's memo. Teva is  2 replying that they do customer audits, sending  3 regular questionnaires and how they're going  4 about it, right?  5 A. Yes.  6 Q. The representative for Watson  7 said how they do the risk assessment based on  8 sales history and quotas, correct?  9 A. Yes, that's what it says.  10 Q. Customers have to fill out  11 questionnaires, and they described their process  12 at the meeting, right?  13 A. Looks that way, yes.  14 Q. AmerisourceBergen is a  15 distributor and they're sharing what they're  16 doing at that point in time, right?  17 MR. SCHACK: Objection.  18 THE WITNESS: It does talk to  19 AmerisourceBergen, yes.  20 BY MR. BUCHANAN:  21 Q. Okay. It further notes there was  22 a "general discussion included an important  23 point for companies involved in SOMS program  24 should document their thought process," right?</p>	<p style="text-align: right;">Page 480</p> <p>1 industry association meetings concerning SOMS  2 and anti-diversion efforts?  3 A. Those are the only two that I can  4 recall.  5 Q. Okay.  6 A. Other than conferences, you know,  7 industry conferences.  8 Q. My last document for you today.  9 MR. BUCHANAN: Do I have a few  10 more minutes. How much time have I  11 used?  12 THE VIDEOGRAPHER: Six hours, six  13 minutes.  14 MR. BUCHANAN: Okay.  15 (Document marked for  16 identification as Par-Norton Deposition  17 Exhibit No. 27.)  18 BY MR. BUCHANAN:  19 Q. Passing you, ma'am, Exhibit 27.  20 Exhibit 27 is a PowerPoint you put together in  21 2014. I guess this is shortly before you move  22 on to HD Smith, right?  23 A. Yes.  24 Q. Okay. Attached you'll find</p>
<p style="text-align: right;">Page 479</p> <p>1 A. Yes, that's what it says.  2 Q. And these are just general  3 discussions and suggestions from company to  4 company about how to manage their SOMS program,  5 right?  6 MS. VANNI: Object to form.  7 THE WITNESS: I don't know  8 exactly what it means. I would assume  9 docu -- you know, document your due  10 diligence.  11 BY MR. BUCHANAN:  12 Q. Right.  13 Additionally, general discussion  14 included an important point, right?  15 You see that?  16 A. Mm-hmm, yes, that's what it says.  17 Q. For companies involved in SOMS  18 programs to document their thought process.  19 Did I read that correctly?  20 A. Yes, that's what it says.  21 Q. Apart from your attendance at  22 industry meetings, the New Jersey Pharmaceutical  23 Industry Group and the anti-diversion working  24 group, did you attend other groups like this</p>	<p style="text-align: right;">Page 481</p> <p>1 presentation from the recent Buzzeo PDMA  2 seminar.  3 Do you see that?  4 A. Yes.  5 Q. Okay. Is this a presentation you  6 prepared?  7 A. Not this entire thing, no.  8 Q. Oh, fair enough. I mean,  9 there's -- this is a compilation of  10 presentations from that day, but this looks like  11 it's the seminar book, right?  12 A. Yes.  13 Q. Okay. Let me take you to where I  14 think yours is and you can confirm that for us.  15 It's 1059.290.  16 A. Yes, that's correct.  17 Q. Okay. And so this is you  18 presenting at the consultant -- the conference  19 for one of the consultants who came and did the  20 inspection at your facility earlier, right?  21 A. This particular consultant has a  22 regular conference. A lot of times they have  23 DEA actually attend their conference. In this  24 particular instance, they did not, and I was</p>

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<p style="text-align: right;">Page 482</p> <p>1 asked to speak at it.</p> <p>2 Q. And what you wrote here is</p> <p>3 "Developing a robust suspicious order monitoring</p> <p>4 program," right?</p> <p>5 A. Yes.</p> <p>6 Q. And did you deliver this</p> <p>7 presentation?</p> <p>8 A. I did.</p> <p>9 Q. And this was a presentation to</p> <p>10 manufacturers, wholesalers, distributors, people</p> <p>11 in the industry concerning controlled</p> <p>12 substances?</p> <p>13 A. A very small group of them, yes.</p> <p>14 Q. Okay. And where was it?</p> <p>15 A. I believe it was in Florida.</p> <p>16 Q. Okay.</p> <p>17 A. I'm not positive. Actually, it</p> <p>18 might have been in Maryland.</p> <p>19 Q. Okay. At page 291, suspicious</p> <p>20 order monitoring, you again note "DEA's Closed</p> <p>21 Loop Distribution System," right?</p> <p>22 A. Yes.</p> <p>23 Q. It's got to be a "Legitimate</p> <p>24 Medical Need, by an Individual Practitioner</p>	<p style="text-align: right;">Page 484</p> <p>1 Q. Reducing Risk.</p> <p>2 Protecting Reputation, that's</p> <p>3 another reason to do it, I guess, right?</p> <p>4 A. Yes.</p> <p>5 MS. VANNI: Object to form.</p> <p>6 THE WITNESS: Basically, you</p> <p>7 don't want to have any DEA violations.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. "Preventing Violations"?</p> <p>10 A. Mm-hmm.</p> <p>11 Q. "Guarding Your Company &amp; Your</p> <p>12 License," right?</p> <p>13 A. The wording with guarding was</p> <p>14 talking about building in layers of security</p> <p>15 into your program.</p> <p>16 Q. And I mean how about, you know,</p> <p>17 making sure that we don't fuel the second</p> <p>18 epidemic anymore; that would be a good reason to</p> <p>19 do it, right?</p> <p>20 MS. VANNI: Objection.</p> <p>21 THE WITNESS: Not the case, but,</p> <p>22 yes.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Not the case, that's not a good</p>
<p style="text-align: right;">Page 483</p> <p>1 Acting in the Usual Course of His or Her</p> <p>2 Professional Practice," right?</p> <p>3 A. Yes.</p> <p>4 Q. You also note "Being a Good</p> <p>5 Corporate Citizen," right?</p> <p>6 A. Yes, because that's how I look at</p> <p>7 things, yes.</p> <p>8 Q. Doing everything in our power to</p> <p>9 prevent abuse and diversion, right?</p> <p>10 MS. VANNI: Objection.</p> <p>11 THE WITNESS: Always looking to</p> <p>12 improve and do more is what my goal is</p> <p>13 personally.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. And what the company's statement</p> <p>16 about its corporate responsibility through your</p> <p>17 letter in October of 2018 was we have to do</p> <p>18 everything we can, right?</p> <p>19 MS. VANNI: Objection.</p> <p>20 THE WITNESS: I believe so.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. "Reducing Risk," that's good,</p> <p>23 right?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 485</p> <p>1 reason?</p> <p>2 MS. VANNI: Objection.</p> <p>3 THE WITNESS: No, it's not the</p> <p>4 case as to what the company was doing.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Okay. And then 1059.296, you</p> <p>7 talk about "Robust Data Analysis Tool," right?</p> <p>8 A. Yes.</p> <p>9 Q. One of the things you do is</p> <p>10 "Receive Regular Data Feeds," right?</p> <p>11 A. Yes.</p> <p>12 Q. Those data feeds should be the</p> <p>13 sales to direct customer, first one, right?</p> <p>14 A. Correct.</p> <p>15 Q. Next thing is to "Chargeback</p> <p>16 Data," right?</p> <p>17 A. Yes, that's what it says.</p> <p>18 Q. This is what you're teaching</p> <p>19 people, right?</p> <p>20 A. Yes.</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: To look at this.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. At this industry meeting, right?</p>

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<p style="text-align: right;">Page 486</p> <p>1 A. To look at this, yes.</p> <p>2 Q. To look at chargeback data so you</p> <p>3 can, what, one, know your customer, right?</p> <p>4 A. Yes.</p> <p>5 Q. And their customer, right?</p> <p>6 A. Correct.</p> <p>7 Q. And their customer, right?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: That's what it</p> <p>10 says.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. That's what you wrote.</p> <p>13 A. Know as much as you can based on</p> <p>14 the data that's available to you.</p> <p>15 Q. It's what you wrote and what you</p> <p>16 presented, ma'am, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Chargeback data, to know your</p> <p>19 customer and their customer and their customer,</p> <p>20 correct?</p> <p>21 A. Yes.</p> <p>22 Q. "Dispensing Data," another</p> <p>23 category, right?</p> <p>24 A. That's what I wrote, yes.</p>	<p style="text-align: right;">Page 488</p> <p>1 A. Right.</p> <p>2 Q. And you've got the -- I guess the</p> <p>3 cute cartoon, I don't know if that's Sherlock</p> <p>4 Holmes or someone there on the right?</p> <p>5 A. Look to your customer.</p> <p>6 Q. There you go.</p> <p>7 A. Look at your customer closely.</p> <p>8 Q. Know your customer again, right?</p> <p>9 A. Yes.</p> <p>10 Q. And so, first, know your customer</p> <p>11 by virtue of data feeds, that was your prior</p> <p>12 slide, correct?</p> <p>13 A. Correct.</p> <p>14 Q. Next, know your customer by</p> <p>15 on-site visits, right?</p> <p>16 A. Right. And all this is</p> <p>17 repetitive of things that DEA -- suggestions</p> <p>18 that they were making.</p> <p>19 Q. This is a presentation you're</p> <p>20 making outside the company to those in industry,</p> <p>21 fair?</p> <p>22 A. Yes.</p> <p>23 Q. And you thought these were</p> <p>24 important points to highlight, fair?</p>
<p style="text-align: right;">Page 487</p> <p>1 Q. These are the information feeds</p> <p>2 that the company should be taking in for</p> <p>3 suspicious order monitoring system, correct?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 THE WITNESS: These are</p> <p>6 suggestions to companies for things that</p> <p>7 they can add to their suspicious order</p> <p>8 monitoring program.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. And with regard to dispensing</p> <p>11 data, what you told people, look at national</p> <p>12 average or actual cleansed dispensing data,</p> <p>13 right?</p> <p>14 A. Yes.</p> <p>15 Q. And use that to help set a</p> <p>16 standard for long-term levels, correct?</p> <p>17 A. That's what it says, yes.</p> <p>18 Q. Can we go to the next page.</p> <p>19 Customer due diligence visits,</p> <p>20 right?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. This is the next thing</p> <p>23 you're telling people that they should do,</p> <p>24 right?</p>	<p style="text-align: right;">Page 489</p> <p>1 A. To reiterate what I had heard DEA</p> <p>2 say, yes.</p> <p>3 Q. And, really, we had seen those in</p> <p>4 your own writings well before the meeting in</p> <p>5 March of 2013, correct?</p> <p>6 A. Yes, the improvements that I</p> <p>7 wanted to make.</p> <p>8 Q. That's a yes answer, ma'am?</p> <p>9 A. Yes.</p> <p>10 Q. Those are the -- you knew that</p> <p>11 these were important components as part of a SOM</p> <p>12 process even before you sat down with the DEA in</p> <p>13 March of 2013, correct?</p> <p>14 A. Again --</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: -- they aren't</p> <p>17 required, they aren't required by DEA.</p> <p>18 They are suggested improvements.</p> <p>19 MR. BUCHANAN: Move to strike.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. You knew they were important</p> <p>22 components of a SOM program before you sat with</p> <p>23 the DEA in March of 2013, we looked at your</p> <p>24 documents, right?</p>

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<p style="text-align: right;">Page 490</p> <p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: They were my</p> <p>3 suggestions for improvement.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. In fact, these were items that</p> <p>6 were listed under a risk assessment of 25, 25,</p> <p>7 the most severe --</p> <p>8 A. Yes.</p> <p>9 Q. -- risk because you didn't have</p> <p>10 these elements in place prior to November of</p> <p>11 2013, right?</p> <p>12 A. They're not required by DEA.</p> <p>13 Q. Not a matter of whether they're</p> <p>14 required, ma'am.</p> <p>15 A. It is.</p> <p>16 Q. The statute, the statute states</p> <p>17 you must maintain effective controls against</p> <p>18 diversion, correct?</p> <p>19 A. And we did, yes.</p> <p>20 Q. Just answer my question.</p> <p>21 A. Yes.</p> <p>22 Q. That's what the statute says?</p> <p>23 A. Yes.</p> <p>24 Q. Not and we did?</p>	<p style="text-align: right;">Page 492</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Is this being presented in</p> <p>3 November of 2014?</p> <p>4 A. It is what I presented.</p> <p>5 Q. Okay.</p> <p>6 A. And it was presented as</p> <p>7 suggestions, and that's how I was asked to</p> <p>8 present it as well.</p> <p>9 Q. And what we have here are, look</p> <p>10 in the parking lot, right?</p> <p>11 A. Again, all things that DEA said</p> <p>12 during conferences as suggestions for companies.</p> <p>13 Q. These are your words, right?</p> <p>14 A. Yes.</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: Suggestions, yes.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. These are your words, correct?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: This is my guidance</p> <p>21 to industry for suggestions of things</p> <p>22 that they can look at to add to what's</p> <p>23 required by the regulation.</p> <p>24 BY MR. BUCHANAN:</p>
<p style="text-align: right;">Page 491</p> <p>1 A. And we did.</p> <p>2 MS. VANNI: Objection.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. That's not the question. The</p> <p>5 statute says you must maintain effective</p> <p>6 controls against diversion, correct?</p> <p>7 MS. KOSKI: Object to form.</p> <p>8 THE WITNESS: Yes.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. Before the DEA sat with you in</p> <p>11 March of 2013, you, as the head of DEA</p> <p>12 compliance with oversight of SOM by early 2013,</p> <p>13 had outlined a number of things the company</p> <p>14 needed to do to revamp its SOM, correct?</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: I had outlined a</p> <p>17 number of things I wanted to improve.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Fair enough. And what you did</p> <p>20 here in 2014 is you went out and told industry,</p> <p>21 peers, distributors, others, these are the</p> <p>22 elements of an effective program, correct?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 THE WITNESS: No. These are --</p>	<p style="text-align: right;">Page 493</p> <p>1 Q. So let's look at this one.</p> <p>2 "Observe parking lot for suspicious activity,</p> <p>3 license plates from multiple states, long lines,</p> <p>4 security guards, etc.," right?</p> <p>5 A. Yes.</p> <p>6 Q. If pharmacy, are most controlled</p> <p>7 product prescriptions written by a handful of</p> <p>8 physicians? Same prescription? Same</p> <p>9 combination? Do they follow up with physicians?</p> <p>10 All reasonable things to do, right?</p> <p>11 MS. VANNI: Object to form.</p> <p>12 THE WITNESS: All good</p> <p>13 suggestions, yes.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. All things that you thought</p> <p>16 worthy to highlight in your presentation about</p> <p>17 this topic for a robust suspicious order</p> <p>18 monitoring system in November of 2014, correct?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: Ways to enhance the</p> <p>21 program, yes.</p> <p>22 MR. BUCHANAN: I think I'm off,</p> <p>23 so with that, let me just check with my</p> <p>24 colleagues. I've gone over my allotted</p>



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<p style="text-align: right;">Page 494</p> <p>1 time, ma'am. I would have loved to have 2 spent more time with you. 3 THE WITNESS: I'm sure. 4 MR. BUCHANAN: Maybe we'll have a 5 chance to talk further. Thank you very 6 much. 7 THE VIDEOGRAPHER: Going off the 8 record, 5:03 p m. 9 (Brief recess.) 10 THE VIDEOGRAPHER: We're now 11 going back on the record. The time is 12 5:39 p m. 13 BY MR. YOUNG: 14 Q. Hi, Ms. Norton. My names is 15 James Young, and I'll try to speak quickly since 16 we only have 45 minutes, though intelligibly. 17 I'm going to talk to you about 18 your experience at HD Smith. So and you have 19 different counsel with you now, who is actually 20 representing HD Smith, Mr. Leeder. 21 A. Yes. 22 Q. So at some point in time, you 23 went to work for HD Smith, I take it? 24 A. Yes, I did.</p>	<p style="text-align: right;">Page 496</p> <p>1 at HD Smith? 2 A. Approximately 190. 3 Q. Okay. And your title changed 4 from director to vice president? 5 A. Correct. 6 Q. Were your job duties essentially 7 the same at both Qualitest and HD Smith, or was 8 there some distinction? 9 A. There were definite differences 10 since it was a manufacturer versus a wholesaler. 11 Q. You testified earlier with regard 12 to Exhibit Number 2, which is the summary of the 13 suspicious order monitoring experience that I 14 think you prepared, I think you testified 15 earlier that some of the representations in here 16 were slightly embellished or not exactly 17 accurate because you were trying to get the job 18 at HD Smith. 19 Do you recall that testimony? 20 MR. LEEDER: Object to form. 21 THE WITNESS: Yes, I do recall 22 that testimony. 23 BY MR. YOUNG: 24 Q. And do you know of the top of</p>
<p style="text-align: right;">Page 495</p> <p>1 Q. Do you recall the date that you 2 began employment there? 3 A. 2014 through 2016. 4 Q. How is it that you came to be 5 employed at HD Smith? Did you answer an ad, 6 were you recruited, did you talk to somebody 7 about a job? 8 A. I believe I got a call from a 9 recruiter and applied, was interested in 10 Illinois. My husband worked for AbbVie, and 11 they had a facility in Illinois, so was looking 12 to kind of have two of us in one place for a 13 change and also for the promotion. 14 Q. And I wanted to ask you about 15 that. You mentioned on your earlier testimony 16 that it was actually a promotion from your 17 current job at Qualitest. 18 Do you mean that in title or in 19 salary or both? 20 A. In both. 21 Q. Okay. What was your salary at 22 Qualitest, when you left? 23 A. I believe it was 172. 24 Q. And what was your starting salary</p>	<p style="text-align: right;">Page 497</p> <p>1 your head which portions or provisions of this 2 summary in Exhibit 2 were -- are not completely 3 accurate? 4 MR. LEEDER: Can you provide her 5 a copy. 6 THE WITNESS: Yeah, not without 7 reviewing. 8 MR. YOUNG: It's Exhibit 2. It 9 wasn't my exhibit. 10 MR. LEEDER: Here, I can share 11 it. 12 MR. YOUNG: I just happen to have 13 this. 14 BY MR. YOUNG: 15 Q. So and I guess I'll direct your 16 attention to a couple specific things. On the 17 Qualitest section which begins, in my version at 18 least, on page 2, there is reference in here to 19 using sales and chargeback data, it's in the 20 second full paragraph, in the middle. It says, 21 "Sales and chargeback data are both used," and I 22 think on earlier examination you hedged a bit 23 and suggested that chargeback data may not have 24 been used during your tenure at Qualitest?</p>

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<p style="text-align: right;">Page 498</p> <p>1 MR. LEEDER: Object to form.</p> <p>2 THE WITNESS: I know that we used</p> <p>3 -- we did look into sale -- to</p> <p>4 chargeback data. I don't recall when it</p> <p>5 was actually implemented, if it was</p> <p>6 implemented before I left or if it was</p> <p>7 implemented after I left. I don't</p> <p>8 recall exactly. I know there were</p> <p>9 struggles with getting the data and</p> <p>10 getting it in a format that we could</p> <p>11 use.</p> <p>12 BY MR. YOUNG:</p> <p>13 Q. This document was prepared while</p> <p>14 you were still employed at Qualitest, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And the specific language is</p> <p>17 sales and chargeback data are both used,</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. And that would suggest to me</p> <p>21 that, in fact, both sales and chargeback data</p> <p>22 are used at Qualitest?</p> <p>23 A. Agreed.</p> <p>24 Q. Okay. But is it your reflection</p>	<p style="text-align: right;">Page 500</p> <p>1 Huntsville/Madison County?</p> <p>2 A. I was actually contacted by them.</p> <p>3 They were really looking for a donation from</p> <p>4 Qualitest. That was their initial goal. They</p> <p>5 were calling all local companies and asking for</p> <p>6 donations, and the woman asked me if I would</p> <p>7 like to attend one of their meetings, and I did</p> <p>8 and found it to be very informative. Local</p> <p>9 police officers were presenting on things they</p> <p>10 were seeing in the community, and, basically,</p> <p>11 that's how I got into the group.</p> <p>12 Q. And so you put it to this</p> <p>13 document that you gained diversion information</p> <p>14 through your -- both your NADDI/DEA conferences</p> <p>15 and through this position as a board member.</p> <p>16 What type of information were you exposed to as</p> <p>17 a board member of that organization, diversion</p> <p>18 specific information?</p> <p>19 A. I mean, more just things that</p> <p>20 were being abused or seen in the area, in the</p> <p>21 very local area, because it was a township</p> <p>22 organization, so just things that the local</p> <p>23 police and the narcotics task force were seeing</p> <p>24 being abused or diverted, so marijuana even they</p>
<p style="text-align: right;">Page 499</p> <p>1 and recollection today that either sales or</p> <p>2 chargeback data was not used by Qualitest during</p> <p>3 your tenure there?</p> <p>4 MS. VANNI: Objection to form.</p> <p>5 THE WITNESS: I wouldn't have</p> <p>6 lied about that in this document, so it</p> <p>7 must have been in use before I left, but</p> <p>8 I didn't recall it being used at the</p> <p>9 time. I thought -- I thought that it</p> <p>10 was still under research when I left for</p> <p>11 some reason, I had that in my head.</p> <p>12 BY MR. YOUNG:</p> <p>13 Q. Okay. There's also reference in</p> <p>14 the first full paragraph, the very last sentence</p> <p>15 under Qualitest, it says that you gained</p> <p>16 additional diversion information through</p> <p>17 conferences and through your position as a board</p> <p>18 member for the Partnership for a Drug Free</p> <p>19 Community in Huntsville/Madison County. I'm</p> <p>20 sorry. It's not the last sentence, it's the</p> <p>21 second to last sentence.</p> <p>22 A. Yes, that's correct.</p> <p>23 Q. What led you to join the board of</p> <p>24 the Partnership for Drug Free Community in</p>	<p style="text-align: right;">Page 501</p> <p>1 talked about, some of the things that they were</p> <p>2 seeing that were more gang related, that type of</p> <p>3 thing.</p> <p>4 Q. Do you recall whether any of the</p> <p>5 items that were being diverted were the items</p> <p>6 that Qualitest manufactured or distributed at</p> <p>7 that time, for example, Vicodin?</p> <p>8 A. I think that there was mention of</p> <p>9 those products, not necessarily the Qualitest</p> <p>10 brand, but those products generally.</p> <p>11 Q. Did you ever take any information</p> <p>12 from that organization and go back to Qualitest</p> <p>13 and investigate or research whether or not there</p> <p>14 were issues relating to diversion of Qualitest</p> <p>15 products?</p> <p>16 MS. VANNI: Object to form.</p> <p>17 THE WITNESS: I presented that</p> <p>18 information, some of the information</p> <p>19 that I received at some of our</p> <p>20 operations leadership team meetings. I</p> <p>21 think one meeting, maybe two I presented</p> <p>22 at, but I wasn't going back and looking</p> <p>23 for diversion because we didn't have --</p> <p>24 I didn't see any gap that this could</p>

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<p style="text-align: right;">Page 502</p> <p>1 have gone out of.</p> <p>2 BY MR. YOUNG:</p> <p>3 Q. Okay. On earlier testimony you</p> <p>4 talked about towards the end of your tenure at</p> <p>5 Qualitest there was an issue -- I shouldn't say</p> <p>6 an issue -- there was an inquiry or</p> <p>7 investigation by the DEA and U.S. Attorney's</p> <p>8 Office.</p> <p>9 Do you recall that testimony?</p> <p>10 A. Yes.</p> <p>11 Q. That happened right as you were</p> <p>12 ending your employment with Qualitest.</p> <p>13 Did you share information about</p> <p>14 that issue with HD Smith upon joining HD Smith?</p> <p>15 MR. LEEDER: Object to form.</p> <p>16 THE WITNESS: I don't believe so.</p> <p>17 BY MR. YOUNG:</p> <p>18 Q. Did it ever come up at HD Smith</p> <p>19 during your employment with HD Smith about this</p> <p>20 U.S. Attorney DEA investigation at Qualitest?</p> <p>21 A. I don't believe so.</p> <p>22 Q. How long did you work for HD</p> <p>23 Smith?</p> <p>24 A. For a little over a year.</p>	<p style="text-align: right;">Page 504</p> <p>1 related, basically about my time at the company</p> <p>2 and was never given a reason.</p> <p>3 Q. Did you have an exit interview</p> <p>4 from HD Smith?</p> <p>5 A. No. That was basically the only</p> <p>6 meeting that I had.</p> <p>7 Q. Were any of the comments either</p> <p>8 made to you during that meeting or made by you</p> <p>9 at that meeting memorialized in writing?</p> <p>10 MR. LEEDER: Object to form.</p> <p>11 THE WITNESS: I don't know.</p> <p>12 BY MR. YOUNG:</p> <p>13 Q. Do you have a copy of the</p> <p>14 severance agreement that you were provided? Do</p> <p>15 you currently maintain --</p> <p>16 A. I had, I don't know if I have it</p> <p>17 currently.</p> <p>18 Q. How much were you paid in</p> <p>19 severance?</p> <p>20 A. I don't know offhand.</p> <p>21 Q. And were you walked out of the</p> <p>22 building? Was it like your last day?</p> <p>23 A. It was, yes.</p> <p>24 Q. Did you have an opinion or theory</p>
<p style="text-align: right;">Page 503</p> <p>1 Q. And what led you to leave your</p> <p>2 employment with HD Smith?</p> <p>3 A. Basically, there was a -- I was</p> <p>4 let go.</p> <p>5 Q. Were you let go, or were you</p> <p>6 terminated?</p> <p>7 A. Well, I got a severance, so I</p> <p>8 guess I would call that let go. Terminated</p> <p>9 usually means no severance and you're gone.</p> <p>10 Q. Walk me through the events that</p> <p>11 led to your departure from HD Smith. Did</p> <p>12 someone approach you and say we're going to have</p> <p>13 to cease your employment?</p> <p>14 A. I was basically walked into a</p> <p>15 conference room thinking I was going to a</p> <p>16 meeting, and when I got into the meeting, my</p> <p>17 boss was there, HR was there, and there was</p> <p>18 outside counsel on the phone, and I was told</p> <p>19 that I wasn't a good fit for the company. I</p> <p>20 asked repeatedly for reasons and was not given</p> <p>21 any reasons, was told the circumstances of</p> <p>22 severance, that was explained to me. I was</p> <p>23 interviewed by the attorney afterwards, asked</p> <p>24 all kinds of questions, SOMS related, license</p>	<p style="text-align: right;">Page 505</p> <p>1 as to why you were being let go from HD Smith at</p> <p>2 that time?</p> <p>3 MR. LEEDER: Object to form.</p> <p>4 THE WITNESS: The only -- the</p> <p>5 only opinion that I could give was a</p> <p>6 license related issue. We were</p> <p>7 outsourcing licensing at the time, and I</p> <p>8 had some challenges with the company</p> <p>9 that was handling the licensing. We had</p> <p>10 some gaps in licensing that basically</p> <p>11 when I investigated the company that was</p> <p>12 handling the licensing, I provided a</p> <p>13 presentation to my supervisor suggesting</p> <p>14 that we should not use them any longer.</p> <p>15 He disagreed. We continued to use them,</p> <p>16 and we had a state license that expired.</p> <p>17 That happened right before I was let go,</p> <p>18 so I made an assumption that that could</p> <p>19 be what it was, but it was never</p> <p>20 confirmed.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Who was that company that you</p> <p>23 outsourced to?</p> <p>24 A. SLS, State Licensing Services.</p>

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<p style="text-align: right;">Page 506</p> <p>1 Q. Were you critical of HD Smith's</p> <p>2 compliance program during your tenure at HD</p> <p>3 Smith?</p> <p>4 MR. LEEDER: Object to form.</p> <p>5 THE WITNESS: I would not say</p> <p>6 that I was critical so much as, again, I</p> <p>7 was looking for improvements to the</p> <p>8 program, as with anyplace that I go and,</p> <p>9 you know, handle compliance. So there</p> <p>10 were improvements that I wanted to make,</p> <p>11 yes.</p> <p>12 BY MR. YOUNG:</p> <p>13 Q. How about specifically with</p> <p>14 regard to the suspicious order monitoring system</p> <p>15 or program that HD Smith had in place, when you</p> <p>16 first began your employment with HD Smith, what</p> <p>17 was your opinion or assessment of their SOMS</p> <p>18 program?</p> <p>19 A. When I first came on, I was very</p> <p>20 impressed with the level of knowledge that the</p> <p>21 employees had with their backgrounds, the ones</p> <p>22 that were, you know, people that were</p> <p>23 investigating the orders and that were out in</p> <p>24 the field. I also thought that there were very</p>	<p style="text-align: right;">Page 508</p> <p>1 system in place was compliant with the CSA?</p> <p>2 A. Yes, that's correct.</p> <p>3 Q. And if that system continued</p> <p>4 without any changes or modifications that</p> <p>5 wouldn't be an issue from a legal or regulatory</p> <p>6 basis, correct?</p> <p>7 MR. LEEDER: Object to form.</p> <p>8 THE WITNESS: Not from a legal or</p> <p>9 regulatory basis, I didn't believe that</p> <p>10 was the case.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Okay. Did you engage in a</p> <p>13 project to evaluate and improve the -- what's</p> <p>14 called the CSOMP program, the SOMS program?</p> <p>15 A. Absolutely, yes, I did.</p> <p>16 Q. Okay. I'm going to show you I</p> <p>17 think we're on Exhibit 28, and it is going to be</p> <p>18 my internal Exhibit 12. Put a label on it here</p> <p>19 for you.</p> <p>20 (Document marked for</p> <p>21 identification as Par-Norton Deposition</p> <p>22 Exhibit No. 28.)</p> <p>23 BY MR. YOUNG:</p> <p>24 Q. That's called or it's captioned a</p>
<p style="text-align: right;">Page 507</p> <p>1 good tools that we had available to us. We had</p> <p>2 dispensing data that was scrubbed from patient</p> <p>3 information -- of patient information removed,</p> <p>4 and we had people that were really good from an</p> <p>5 IT perspective that were able to put that data</p> <p>6 in a fashion that was really usable.</p> <p>7 Q. The system that was in place for</p> <p>8 suspicious order monitoring on your first day,</p> <p>9 did you ever make a determination as to whether</p> <p>10 or not that system was in compliance or out of</p> <p>11 compliance with the legal and regulatory</p> <p>12 requirements of the Controlled Substances Act?</p> <p>13 MR. LEEDER: Objection to form.</p> <p>14 THE WITNESS: Yes, I basically</p> <p>15 felt that it was -- it did meet the</p> <p>16 regulation, but it was similar. It</p> <p>17 basically looked at threshold amount and</p> <p>18 then pattern and frequency afterwards,</p> <p>19 and I wanted it to meet pattern and</p> <p>20 frequency from an electronic</p> <p>21 perspective.</p> <p>22 BY MR. YOUNG:</p> <p>23 Q. Okay. So your opinion at the</p> <p>24 time that you began with HD Smith was that the</p>	<p style="text-align: right;">Page 509</p> <p>1 "Project Initiation Form."</p> <p>2 Does that look familiar to you?</p> <p>3 A. Yes, it does.</p> <p>4 Q. And it has a date on it revised</p> <p>5 June 30th, 2015.</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. What do you recall about</p> <p>9 this particular document, Project Initiation</p> <p>10 Form?</p> <p>11 A. This was the form that was used</p> <p>12 to start an IT project at the company, so these</p> <p>13 were things that I wanted to add to our program</p> <p>14 to enhance it, and these were -- it's detailed</p> <p>15 on here.</p> <p>16 Q. Okay. In the middle of this</p> <p>17 first page, there is a section that says "Impact</p> <p>18 if project not performed," and there's some</p> <p>19 numbered items underneath there.</p> <p>20 Can you read for me what number 1</p> <p>21 is under impact?</p> <p>22 A. Yes. "Significant Regulatory</p> <p>23 Risk. Current program does not meet minimum DEA</p> <p>24 requirements (especially Pattern &amp; Frequency)."</p>

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<p style="text-align: right;">Page 510</p> <p>1 Q. Okay. So let's just go back for 2 a second. I just asked you before whether or 3 not the current program met the minimum DEA 4 requirements from a legal and regulatory 5 perspective, and I believe your answer was, yes, 6 it did? 7 A. Yes. 8 Q. Here is a document that I believe 9 you prepared or at least you were the project 10 lead on? 11 A. Yes. 12 Q. And it says quite the opposite, 13 correct? 14 A. Yes. 15 Q. So which one of these is correct, 16 your prior testimony or this document? 17 MR. SCHACK: Objection. 18 THE WITNESS: So the DEA reg had 19 the requirement for orders, order 20 quantity, you know, frequency and 21 pattern. I knew we were doing pattern 22 and frequency as well when the order 23 pended, but I was worried about being 24 able to defend that if -- I think in</p>	<p style="text-align: right;">Page 512</p> <p>1 A. This real -- 2 MR. LEEDER: Object to form. 3 THE WITNESS: This was part of 4 the improvement project. We had also 5 implemented the company had implemented 6 SAP prior to my arrival, and so there 7 were still some -- some challenges, some 8 bugs being worked out of the system 9 because it was so new, the integration 10 with SAP, so I wanted to address those 11 items as well. 12 BY MR. YOUNG: 13 Q. Number 2 on this list of impact 14 if this project was not performed is -- can you 15 read that for us number 2, not the bullet but 16 the actual number 2. 17 A. "Risk to the Company Reputation 18 and patients if product is distributed to 19 illegitimate sources." 20 Q. So walk me through the risk to 21 patients if the product is distributed to 22 illegitimate sources, what would the risk be to 23 patients? 24 A. If the product, and this was</p>
<p style="text-align: right;">Page 511</p> <p>1 most cases we would be able to because 2 we had -- we had proof that the pattern 3 and frequency was being looked at after 4 the fact, but the pattern and frequency 5 was not what was stopping the order 6 initially, and so I wanted to be 100% 7 sure that it wasn't something. And, 8 again, because different DEA offices, 9 different DEA investigators can 10 interpret things differently, I wanted 11 to make sure that if someone were to 12 look at the system, it would be spelled 13 out clearly up front that it looks at 14 pattern, frequency and volume, and I 15 knew we were doing it behind the scenes, 16 but it wasn't spelled out up front. It 17 didn't stop based on that. 18 BY MR. YOUNG: 19 Q. And so when you determined that 20 the current system at HD Smith did not account 21 for pattern and frequency identification of 22 suspicious orders, is that part of what drove 23 this project or was it a subset of some other 24 evaluation or audit?</p>	<p style="text-align: right;">Page 513</p> <p>1 general -- generally if product goes to an 2 illegitimate source and is repackaged, my 3 thinking was if that illegitimate source were to 4 repackage that product, they might repackage it 5 without the appropriate expiration dating, 6 without the appropriate risk information, so, 7 you know, there is counterfeit product out 8 there. That was kind of my thinking around that 9 line. 10 Q. How about abuse and misuse, 11 overdose, death, any of those, would those have 12 been contemplated in the risk to patients if 13 product is distributed to illegitimate sources? 14 MR. LEEDER: Object to form. 15 BY MR. YOUNG: 16 Q. That's not what you were 17 thinking? 18 A. It would be -- no. It would be a 19 risk, but not to patients. Patients I thought 20 of getting it legitimately. So I was looking at 21 that more from somebody who -- when I say 22 illegitimate, somebody who is doing something 23 with the product they shouldn't be. 24 Q. Is diversion an illegitimate</p>



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<p style="text-align: right;">Page 514</p> <p>1 thing to do with a controlled substance?</p> <p>2 A. Yes.</p> <p>3 Q. And you weren't contemplating</p> <p>4 diversion of product in to people that shouldn't</p> <p>5 have the controlled substances here; that's your</p> <p>6 testimony today?</p> <p>7 MR. LEEDER: Object to form.</p> <p>8 THE WITNESS: That's not what</p> <p>9 this meant. I mean, obviously, if you</p> <p>10 ship it to somebody who is not</p> <p>11 registered and not doing their due</p> <p>12 diligence then, yes, you could have</p> <p>13 diversion or you could have abuse, but</p> <p>14 that's not what this bullet was</p> <p>15 referring to.</p> <p>16 BY MR. YOUNG:</p> <p>17 Q. Aside from these two functions</p> <p>18 that were absent in the CSOMP system, the</p> <p>19 pattern and frequency, were there other flaws or</p> <p>20 holes in the CSOMP system at HD Smith that gave</p> <p>21 you concern?</p> <p>22 MR. LEEDER: Object to form.</p> <p>23 THE WITNESS: There were other</p> <p>24 things that needed -- that I wanted to</p>	<p style="text-align: right;">Page 516</p> <p>1 overstating the severity of the situation in</p> <p>2 order to get buy-in from senior management?</p> <p>3 MR. LEEDER: Object to form.</p> <p>4 THE WITNESS: To a certain</p> <p>5 extent, yes.</p> <p>6 BY MR. YOUNG:</p> <p>7 Q. Okay. If we can could pull out</p> <p>8 of that zoom-in and look at Project Objectives,</p> <p>9 which is the top middle, there's another -- so</p> <p>10 the very first item on here of the objectives is</p> <p>11 "Add Pattern &amp; Frequency." We talked about</p> <p>12 that.</p> <p>13 The second one is assess by DEA</p> <p>14 number rather than account number. What's that</p> <p>15 referring to?</p> <p>16 A. So the current -- the system at</p> <p>17 the time kept track of customers and pended</p> <p>18 orders by account number, and a customer could</p> <p>19 have more than one account number, so I wanted</p> <p>20 to do it by DEA number because it was more</p> <p>21 specific to customer and customer location.</p> <p>22 Q. In fact, didn't HD Smith</p> <p>23 determine that there were several instances in</p> <p>24 which the same customer had multiple account</p>
<p style="text-align: right;">Page 515</p> <p>1 improve upon.</p> <p>2 BY MR. YOUNG:</p> <p>3 Q. And I want to really put a fine</p> <p>4 point on this because I think you went through</p> <p>5 this in your earlier testimony suggesting that</p> <p>6 these are improvements. In fact, your</p> <p>7 handwriting -- your words here are "current</p> <p>8 program does not meet minimum DEA requirements."</p> <p>9 That's not an improvement. That's it either</p> <p>10 meets or does not meet, so I need to be really</p> <p>11 clear with you here right now.</p> <p>12 Did the program, at the time you</p> <p>13 wrote Project Initiation Form, this document</p> <p>14 here, did the program meet the DEA requirements</p> <p>15 or not?</p> <p>16 A. Yes.</p> <p>17 Q. So when you said "current program</p> <p>18 does not meet minimum DEA requirements," you</p> <p>19 were wrong?</p> <p>20 A. No. If I had have said that it</p> <p>21 met regulatory requirements, the project</p> <p>22 probably wouldn't have gotten the priority that</p> <p>23 it did, and it wouldn't have moved forward.</p> <p>24 Q. So this is an example of you</p>	<p style="text-align: right;">Page 517</p> <p>1 numbers and thereby received multiple</p> <p>2 thresholds?</p> <p>3 MR. LEEDER: Object to form.</p> <p>4 THE WITNESS: I don't recall any</p> <p>5 specific ones, but it was a practice at</p> <p>6 HD Smith to assign multiple account</p> <p>7 numbers to customers.</p> <p>8 BY MR. YOUNG:</p> <p>9 Q. Okay. In that aspect of the</p> <p>10 CSOMP program, do you feel that that was in or</p> <p>11 out of compliance with the expectations of the</p> <p>12 legal and regulatory requirements of the CSA?</p> <p>13 MR. LEEDER: Object to form.</p> <p>14 THE WITNESS: The regulation does</p> <p>15 not go to that level of detail.</p> <p>16 BY MR. YOUNG:</p> <p>17 Q. Was that an effective system to</p> <p>18 prevent diversion, allowing one customer to have</p> <p>19 multiple account numbers --</p> <p>20 MR. LEEDER: Object to form.</p> <p>21 BY MR. YOUNG:</p> <p>22 Q. -- and receive multiple shipments</p> <p>23 of controlled substances?</p> <p>24 A. It basically meant that the</p>

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<p style="text-align: right;">Page 518</p> <p>1 compliance people had to do more work. That's</p> <p>2 really the impact of that.</p> <p>3 Q. How many compliance people did HD</p> <p>4 Smith have at the time that you began your</p> <p>5 employment there?</p> <p>6 A. We had five, five or six.</p> <p>7 Q. And when you began your</p> <p>8 employment with HD Smith, did you feel that the</p> <p>9 staffing and resources were sufficient to handle</p> <p>10 the legal and regulatory compliance work that</p> <p>11 needed to be done at HD Smith?</p> <p>12 MS. KOSKI: Object to form.</p> <p>13 THE WITNESS: I was worried about</p> <p>14 backups to people.</p> <p>15 BY MR. YOUNG:</p> <p>16 Q. Did you complain to senior</p> <p>17 management or your supervisors that you didn't</p> <p>18 have enough people to do the current job and you</p> <p>19 couldn't take on new tasks?</p> <p>20 MR. LEEDER: Object to form.</p> <p>21 THE WITNESS: No. I did ask for</p> <p>22 additional head count. I didn't say I</p> <p>23 couldn't take on more tasks.</p> <p>24 BY MR. YOUNG:</p>	<p style="text-align: right;">Page 520</p> <p>1 A. I have recollection of items that</p> <p>2 I wanted to improve.</p> <p>3 Q. And were not able to?</p> <p>4 A. No. We were working towards it.</p> <p>5 This project was working towards it.</p> <p>6 Q. Did this project complete prior</p> <p>7 to your departure from HD Smith?</p> <p>8 A. It did not.</p> <p>9 Q. Do you know whether or not this</p> <p>10 project was ever finally implemented?</p> <p>11 A. I'm not sure. That occurred --</p> <p>12 would have occurred after I left.</p> <p>13 Q. Do you know who you replaced at</p> <p>14 HD Smith in the head of compliance?</p> <p>15 A. Yes, George Euson.</p> <p>16 Q. Do you have a opinion on the</p> <p>17 ability and efficacy of George Euson to be the</p> <p>18 chief compliance officer or senior compliance</p> <p>19 department person for HD Smith?</p> <p>20 MR. LEEDER: Object to form.</p> <p>21 THE WITNESS: Absolutely. He's</p> <p>22 one of the best.</p> <p>23 BY MR. YOUNG:</p> <p>24 Q. One of the best in the business?</p>
<p style="text-align: right;">Page 519</p> <p>1 Q. Did you receive additional head</p> <p>2 count when you asked for it?</p> <p>3 A. I did.</p> <p>4 Q. Each and every time?</p> <p>5 A. Yes.</p> <p>6 Q. Did you ever ask for additional</p> <p>7 resources or access to data or services or</p> <p>8 outside vendors in compliance and were denied</p> <p>9 that request by HD Smith?</p> <p>10 MR. LEEDER: Object to form.</p> <p>11 THE WITNESS: None that I can</p> <p>12 recall.</p> <p>13 BY MR. YOUNG:</p> <p>14 Q. So your recollection today is</p> <p>15 that everything at HD Smith from a compliance</p> <p>16 perspective was perfectly in compliance with the</p> <p>17 Controlled Substances Act expectations and</p> <p>18 regulations and law?</p> <p>19 MR. LEEDER: Same objection.</p> <p>20 THE WITNESS: It did meet the</p> <p>21 regulation.</p> <p>22 BY MR. YOUNG:</p> <p>23 Q. You have no critical recollection</p> <p>24 of your time at HD Smith today?</p>	<p style="text-align: right;">Page 521</p> <p>1 A. Yes.</p> <p>2 Q. Is George as capable and</p> <p>3 qualified as you, more so or less so?</p> <p>4 MR. LEEDER: Object to form.</p> <p>5 THE WITNESS: I can't really say</p> <p>6 that one way or the other.</p> <p>7 BY MR. YOUNG:</p> <p>8 Q. Do you know George's background?</p> <p>9 A. I believe he was law enforcement,</p> <p>10 ex-law enforcement. I'm not positive, but I</p> <p>11 think that was his background.</p> <p>12 Q. Do you know if he has any</p> <p>13 advanced degrees, such as yourself, in the</p> <p>14 pharmaceutical sector?</p> <p>15 A. I don't know.</p> <p>16 Q. The second to last bullet point</p> <p>17 is distinguish primary versus secondary account</p> <p>18 when an order pends.</p> <p>19 Can you explain what's meant by</p> <p>20 that objective?</p> <p>21 A. Primary meant that we were the</p> <p>22 primary supplier for that account versus</p> <p>23 secondary meant there were other wholesalers</p> <p>24 that also supplied the account, which was</p>

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<p style="text-align: right;">Page 522</p> <p>1 common.</p> <p>2 Q. And is HD Smith more typically a</p> <p>3 secondary supplier or a primary supplier?</p> <p>4 A. They were more of a secondary</p> <p>5 supplier when I was there.</p> <p>6 Q. Okay. And did HD Smith have the</p> <p>7 ability during your tenure to identify the</p> <p>8 controlled substance utilization of a pharmacy</p> <p>9 from its primary supplier when you were the</p> <p>10 secondary supplier?</p> <p>11 MR. LEEDER: Object to form.</p> <p>12 THE WITNESS: They -- we had that</p> <p>13 question on our customer questionnaire,</p> <p>14 and we utilized that to make a</p> <p>15 determination.</p> <p>16 BY MR. YOUNG:</p> <p>17 Q. Was there any other means or</p> <p>18 method that you could determine the extent of</p> <p>19 controlled substance purchases by a pharmacy's</p> <p>20 primary supplier when you were the secondary</p> <p>21 supplier?</p> <p>22 A. Through the dis --</p> <p>23 MR. LEEDER: Object to form.</p> <p>24 THE WITNESS: Yes, through the</p>	<p style="text-align: right;">Page 524</p> <p>1 one month -- a one month period of time.</p> <p>2 BY MR. YOUNG:</p> <p>3 Q. When you -- when HD Smith takes</p> <p>4 on an initial customer as a new customer, I</p> <p>5 think you mentioned that you have them complete</p> <p>6 a new customer profile form?</p> <p>7 A. Yes.</p> <p>8 Q. Why doesn't HD Smith obtain the</p> <p>9 one-month DUR report on a new customer when</p> <p>10 they're bringing them on board when they're on</p> <p>11 boarding a new customer?</p> <p>12 MR. LEEDER: Object to form.</p> <p>13 BY MR. YOUNG:</p> <p>14 Q. Why don't they do that?</p> <p>15 A. I don't know.</p> <p>16 Q. Would it make sense to you now,</p> <p>17 sitting here today, in light of this litigation</p> <p>18 and everything that you know for a distributor</p> <p>19 to obtain a DUR report for a customer as it</p> <p>20 brings them on, would that be a beneficial piece</p> <p>21 of information to have to evaluate the risk?</p> <p>22 MR. SCHACK: Objection.</p> <p>23 MR. LEEDER: Object to form.</p> <p>24 THE WITNESS: I don't think it</p>
<p style="text-align: right;">Page 523</p> <p>1 dispensing data.</p> <p>2 BY MR. YOUNG:</p> <p>3 Q. Okay. And how often did you</p> <p>4 obtain dispensing date from customers?</p> <p>5 A. Usually if the customer pended,</p> <p>6 we would look at everything that was available</p> <p>7 to us and if a decision couldn't be made one way</p> <p>8 or the other, we would get dispensing data.</p> <p>9 Q. I asked this question of other HD</p> <p>10 Smith witnesses, so I'm compelled to ask you,</p> <p>11 why didn't HD Smith obtain utilization data or</p> <p>12 DUR data from all pharmacy customers? Why did</p> <p>13 you only obtain it after an order was pending?</p> <p>14 Wouldn't it be best practices to obtain all the</p> <p>15 information that you can about a customer?</p> <p>16 MR. LEEDER: Object to form.</p> <p>17 MR. SCHACK: Object to form.</p> <p>18 THE WITNESS: I think it would be</p> <p>19 very difficult for every single</p> <p>20 customer. There's over -- I don't know</p> <p>21 as far as number of DEA -- of customers</p> <p>22 for HD Smith, but there's over a million</p> <p>23 pharmacy registrants in the United</p> <p>24 States, and the dispensing data covered</p>	<p style="text-align: right;">Page 525</p> <p>1 would be beneficial at that point. They</p> <p>2 haven't received any of our products.</p> <p>3 BY MR. YOUNG:</p> <p>4 Q. When HD Smith terminates a</p> <p>5 relationship with a customer, a pharmacy</p> <p>6 customer, obviously, that pharmacy is going to</p> <p>7 seek its purchases elsewhere.</p> <p>8 Does HD Smith inform other</p> <p>9 distributors that it ceased doing business with</p> <p>10 a particular pharmacy?</p> <p>11 MR. LEEDER: Object to form.</p> <p>12 THE WITNESS: I don't recall</p> <p>13 having done that; however, other</p> <p>14 wholesale -- well, I don't know. I</p> <p>15 don't know if we did or not, to be</p> <p>16 honest.</p> <p>17 BY MR. YOUNG:</p> <p>18 Q. Do you know whether or not HD</p> <p>19 Smith has received information from other</p> <p>20 distributors about pharmacies that they've</p> <p>21 ceased doing business with?</p> <p>22 A. I did receive a couple of</p> <p>23 inquiries while I was there.</p> <p>24 Q. Through any of the trade</p>

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<p style="text-align: right;">Page 526</p> <p>1 associations or working groups or Listservs or</p> <p>2 any of the other various pharmaceutical</p> <p>3 distributor or wholesaler organizations, do you</p> <p>4 know whether or not such information is shared</p> <p>5 among distributors of bad actor pharmacies or</p> <p>6 suspicious pharmacies?</p> <p>7 A. No, I mean, that would be</p> <p>8 competitive information, so they wouldn't share</p> <p>9 that.</p> <p>10 Q. Do you know whether or not the</p> <p>11 DEA or any state board of pharmacy has ever</p> <p>12 shared with you information about suspicious</p> <p>13 pharmacies that it was investigating or that it</p> <p>14 had concerns about?</p> <p>15 MR. LEEDER: Object to form.</p> <p>16 THE WITNESS: Not on their own.</p> <p>17 If we conveyed to DEA that we were</p> <p>18 looking at a particular pharmacy or if</p> <p>19 we reported that pharmacy to DEA, they</p> <p>20 have on occasion made comment about</p> <p>21 looking into that particular customer as</p> <p>22 well. It was infrequent because it's</p> <p>23 not like DEA to share that information,</p> <p>24 but the people that I had working for me</p>	<p style="text-align: right;">Page 528</p> <p>1 department conduct investigations in order to</p> <p>2 determine whether or not -- or I should say</p> <p>3 conduct analysis or investigations in order to</p> <p>4 determine whether or not the establishment of</p> <p>5 the initial URLs were sufficient to identify</p> <p>6 suspicious orders?</p> <p>7 MR. LEEDER: Objection.</p> <p>8 THE WITNESS: Yes, they were</p> <p>9 conducting analysis on a daily basis.</p> <p>10 They were constantly looking at</p> <p>11 customers and numbers.</p> <p>12 MR. YOUNG: I want to show you --</p> <p>13 this is going to be number 14 in your</p> <p>14 book. It's going to Exhibit 29. I do</p> <p>15 have copies for you guys. I'm sorry.</p> <p>16 Just trying to get this done as quick as</p> <p>17 possible.</p> <p>18 (Document marked for</p> <p>19 identification as Par-Norton Deposition</p> <p>20 Exhibit No. 29.)</p> <p>21 BY MR. YOUNG:</p> <p>22 Q. This is captioned "Meeting</p> <p>23 Minutes."</p> <p>24 Do you recognize this document?</p>
<p style="text-align: right;">Page 527</p> <p>1 had -- some of them, a couple of them</p> <p>2 had very good working relationships with</p> <p>3 DEA.</p> <p>4 BY MR. YOUNG:</p> <p>5 Q. When HD Smith takes on a new</p> <p>6 customer, how does it know how to set the</p> <p>7 threshold or URL I think is what HD Smith calls</p> <p>8 unit reportable level, how does it know how to</p> <p>9 set the threshold or URL for a new customer?</p> <p>10 A. I know we had a plant URL that</p> <p>11 was an automatic number that was set, so it</p> <p>12 basically got the plant URL.</p> <p>13 Q. Did you have an opinion when you</p> <p>14 joined HD Smith, based on your prior experience</p> <p>15 in the industry or your prior education and</p> <p>16 training, about the particular way in which HD</p> <p>17 Smith established its URLs for new customers?</p> <p>18 MR. SCHACK: Objection.</p> <p>19 THE WITNESS: No I thought the</p> <p>20 information was -- was pretty well</p> <p>21 orchestrated as far as that goes.</p> <p>22 BY MR. YOUNG:</p> <p>23 Q. Did you ever either yourself or</p> <p>24 have your -- the folks in your compliance</p>	<p style="text-align: right;">Page 529</p> <p>1 MR. LEEDER: I just want to note</p> <p>2 for the record that this is after her</p> <p>3 departure from the company.</p> <p>4 BY MR. YOUNG:</p> <p>5 Q. Have you ever seen this document,</p> <p>6 though?</p> <p>7 A. No. I've seen the template used</p> <p>8 previously, but I haven't seen this.</p> <p>9 Q. Okay. I just want to walk</p> <p>10 through this document with you to see -- get</p> <p>11 your reflection on some of the information in</p> <p>12 here. Can we go to page 2, under Number 9 under</p> <p>13 the Agreement, section E, "customers with less."</p> <p>14 MR. SCHACK: Can you identify it</p> <p>15 for the record with a Bates number on</p> <p>16 there.</p> <p>17 MR. YOUNG: Oh, I just handed you</p> <p>18 -- oh, I'm sorry. I just handed it to</p> <p>19 him. Yeah, the Bates range is -- boy,</p> <p>20 if I could read that.</p> <p>21 MR. LEEDER: It's 294884 through</p> <p>22 294886.</p> <p>23 BY MR. YOUNG:</p> <p>24 Q. And it says in Number 9,</p>

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<p style="text-align: right;">Page 530</p> <p>1 "Customers with less than 4 months of sales 2 history will not be checked for pattern and 3 frequency, per Kyle," and I just wanted to get 4 your reflection on during the -- I know this is 5 after your tenure, but while you were at HD 6 Smith, was this the case also that new customers 7 with less than four months sales history would 8 not be checked for pattern and frequency under 9 the CSOMP program? 10 MR. LEEDER: Object to form. 11 THE WITNESS: No. While I was 12 there if the customer order pended, they 13 would automatically check for pattern 14 and frequency as well. 15 BY MR. YOUNG: 16 Q. And I need to clean that up. 17 What you're referring to when you say the order 18 pended is under the CSOMP program at the time, 19 the only criteria that caused an order to pend 20 was the size of the order, right, whether it 21 exceeded the URL? 22 MR. LEEDER: Objection to form. 23 THE WITNESS: Yes. 24</p>	<p style="text-align: right;">Page 532</p> <p>1 MR. LEEDER: Objection to form. 2 MR. SCHACK: Objection to form. 3 BY MR. YOUNG: 4 Q. Just the CSOMP? 5 A. Just the electronic system. It 6 pended based on order quantity, and then they 7 looked at pattern and frequency. 8 Q. Yeah, so -- 9 A. So the first pend would be order 10 quantity. 11 Q. And absent that, there would be 12 no evaluation in CSOMP, correct? 13 MR. SCHACK: Objection. 14 MR. LEEDER: Objection to form. 15 THE WITNESS: There would be 16 other things that were investigated that 17 might pick it up. 18 BY MR. YOUNG: 19 Q. In CSOMP? Give me the factors in 20 CSOMP that would cause an order to be picked up 21 that didn't exceed its URL? 22 MR. SCHACK: Objection. 23 THE WITNESS: When you say "in 24 CSOMP," it wouldn't pend based on it,</p>
<p style="text-align: right;">Page 531</p> <p>1 BY MR. YOUNG: 2 Q. Correct, okay. 3 So if a pharmacy changed 4 substantially its ordering pattern and its 5 ordering frequency but didn't exceed the URL, 6 that would not be caught by the system and not 7 investigated by compliance, correct? 8 MR. SCHACK: Objection. 9 BY MR. YOUNG: 10 Q. So long as the order didn't 11 breach the URL in total, that order would not be 12 evaluated by the CSOMP program? 13 MR. LEEDER: Objection. 14 MR. SCHACK: Objection. 15 THE WITNESS: It's hard to say 16 because it could be caught in other 17 ways. 18 BY MR. YOUNG: 19 Q. Okay. The question is 20 specifically in the CSOMP program, is it your 21 testimony today that the CSOMP program would 22 catch on pattern and frequency during your 23 tenure at HD Smith if an order did not hit its 24 URL?</p>	<p style="text-align: right;">Page 533</p> <p>1 but it would be -- there were other 2 things that the group was doing to check 3 for things like that. 4 BY MR. YOUNG: 5 Q. Explain that to me. Walk me 6 through the process that compli -- we don't have 7 a lot of time, but this is vital to the case to 8 understand this. 9 MR. SCHACK: Objection to the 10 colloquy. 11 BY MR. YOUNG: 12 Q. Go ahead. 13 A. Basically running reports, we 14 would sort the data in all kinds of ways all the 15 time. 16 Q. What are the names of the reports 17 that you would run? 18 A. I don't think they really had 19 names. 20 Q. Nameless reports, okay. 21 Who ran these reports? 22 MR. SCHACK: Objection. 23 THE WITNESS: Usually Kyle. 24 BY MR. YOUNG:</p>

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<p style="text-align: right;">Page 534</p> <p>1 Q. Kyle?</p> <p>2 A. Kyle Rieger.</p> <p>3 Q. Rieger.</p> <p>4 How often were these reports run?</p> <p>5 A. Sporadically. It wasn't -- it</p> <p>6 wasn't a set time, so they would be run, you</p> <p>7 know.</p> <p>8 Q. So nameless, random reports would</p> <p>9 capture pattern and frequency deviations</p> <p>10 sufficient to meet the CSA requirements?</p> <p>11 MR. SCHACK: Objection.</p> <p>12 MR. LEEDER: Objection to form.</p> <p>13 MR. SCHACK: Completely</p> <p>14 inappropriate.</p> <p>15 THE WITNESS: Not every one.</p> <p>16 BY MR. YOUNG:</p> <p>17 Q. Okay. So the CSOMP program was</p> <p>18 an automated program, right?</p> <p>19 A. Yes.</p> <p>20 Q. Is there some functionality in</p> <p>21 the CSOMP program, to your knowledge, today,</p> <p>22 during your tenure with HD Smith or prior to</p> <p>23 that that would have captured pattern and</p> <p>24 frequency without pending for size of the order?</p>	<p style="text-align: right;">Page 536</p> <p>1 position?</p> <p>2 A. I know that there was -- the</p> <p>3 reporting to DEA happened by e-mail usually</p> <p>4 and -- all the time it happened by e-mail.</p> <p>5 Q. Do you know how often those would</p> <p>6 be reported, the frequency?</p> <p>7 A. It wasn't a set -- I mean,</p> <p>8 sometimes it could be one in a month and</p> <p>9 sometimes it could be four in a month, you know,</p> <p>10 it varied.</p> <p>11 Q. And do you know who identified</p> <p>12 the suspicious orders, which particular --</p> <p>13 A. We had people in the field that</p> <p>14 basically would go in to audit those customers,</p> <p>15 and the dispensing data would be run as part of</p> <p>16 that audit, and that's really where it would</p> <p>17 be -- they would be identified.</p> <p>18 Q. In the CSOMP system, do you</p> <p>19 recall Z5 hold on orders? Does that -- does the</p> <p>20 term Z5 mean anything to you?</p> <p>21 A. It does sound familiar, yes.</p> <p>22 It's one of the holds. I'm not sure which one.</p> <p>23 Q. Okay. And what's a hold in the</p> <p>24 CSOMP system?</p>
<p style="text-align: right;">Page 535</p> <p>1 MR. LEEDER: Objection to form</p> <p>2 and foundation.</p> <p>3 MR. SCHACK: Objection.</p> <p>4 THE WITNESS: When I was there,</p> <p>5 no. But prior to that, I don't know. I</p> <p>6 know there was a different system. I</p> <p>7 don't know the details of that system.</p> <p>8 BY MR. YOUNG:</p> <p>9 Q. Do you know what HD Smith did</p> <p>10 prior to implementation of its CSOMP in order to</p> <p>11 identify and report suspicious orders?</p> <p>12 A. I do not.</p> <p>13 Q. You're wholly unaware of that?</p> <p>14 MR. SCHACK: Objection.</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MR. YOUNG:</p> <p>17 Q. Do you know whether or not --</p> <p>18 A. Prior to my coming to the</p> <p>19 company, I know there was a system, I don't know</p> <p>20 the details of it, because it was prior to SAP,</p> <p>21 and when I came, they already had SAP.</p> <p>22 Q. Do you know how the company</p> <p>23 handled the reporting to the DEA of suspicious</p> <p>24 orders prior to George Euson taking his</p>	<p style="text-align: right;">Page 537</p> <p>1 A. It could be a hold for a credit</p> <p>2 reason. It could be a hold for a SOM reason.</p> <p>3 There were several different types of holds that</p> <p>4 the system could have.</p> <p>5 Q. Do you recall during your tenure</p> <p>6 as head of compliance at HD Smith identifying an</p> <p>7 issue with the Z5 hold release?</p> <p>8 A. Not specifically.</p> <p>9 Q. Do you recall identifying that</p> <p>10 too many people in the company had the ability</p> <p>11 to release a Z5 CSOMP hold?</p> <p>12 MR. LEEDER: Objection to form.</p> <p>13 THE WITNESS: Yes, it was one of</p> <p>14 the things that we looked at.</p> <p>15 BY MR. YOUNG:</p> <p>16 Q. Do you know how many people in</p> <p>17 the company when you looked at it you found out</p> <p>18 had the ability to release a Z5 CSOMP hold?</p> <p>19 MR. LEEDER: Objection.</p> <p>20 THE WITNESS: I know that there</p> <p>21 were many. We were -- I was very</p> <p>22 pleased to find out that none of them</p> <p>23 had. Most of them didn't even know they</p> <p>24 had that capability, but there were</p>

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<p style="text-align: right;">Page 538</p> <p>1 quite a few. It was a flaw from SAP.</p> <p>2 BY MR. YOUNG:</p> <p>3 Q. Do you know was it more than 100</p> <p>4 people?</p> <p>5 A. I don't recall.</p> <p>6 Q. Does 448 ring a bell?</p> <p>7 A. Possibly it could have been that</p> <p>8 many, yes.</p> <p>9 Q. Do you know whether or not the HD</p> <p>10 Smith CSOMP systems were always operational, or</p> <p>11 was there a point in time during your tenure</p> <p>12 that the CSOMP systems failed or were</p> <p>13 inoperable?</p> <p>14 A. There were -- as I said earlier,</p> <p>15 there were some bugs with SAP that needed to be</p> <p>16 worked out, and that's one of the things that</p> <p>17 were included -- was included in the projects.</p> <p>18 There was an occasion where orders that should</p> <p>19 have pended didn't pend and our group went back</p> <p>20 and ran reports and did extensive research on</p> <p>21 those orders.</p> <p>22 Q. Do you recall reviewing</p> <p>23 spreadsheets of orders that exceeded a URL but</p> <p>24 did not go through CSOMP and did not pend?</p>	<p style="text-align: right;">Page 540</p> <p>1 analysis, and it's dated February 3rd of 2015.</p> <p>2 Can you read for me what Kyle</p> <p>3 Rieger writes to Durga here?</p> <p>4 A. "Durga, see the attached</p> <p>5 spreadsheet. I came up with this summary based</p> <p>6 on the October 2014 date that you sent to</p> <p>7 Tracey. I wanted to touch base with you on this</p> <p>8 and see if there is an easier way to get to this</p> <p>9 information. Manually breaking down the report</p> <p>10 you sent is extremely time consuming.</p> <p>11 Essentially, I'm looking for a list of DU's</p> <p>12 shipped over the URL where the account also had</p> <p>13 some orders that did not go through CSOMP. I</p> <p>14 don't think I need individual order detail just</p> <p>15 as long as we can see what their total number of</p> <p>16 DU's shipped vs. their URL."</p> <p>17 Q. Okay. And the attachment behind</p> <p>18 it is a spreadsheet, and I'm not going to have</p> <p>19 you -- we don't have the time to go through it,</p> <p>20 but can you take a look quickly at the</p> <p>21 spreadsheet at the top of the titles of the</p> <p>22 columns. Does it look familiar to you?</p> <p>23 The first page of this just</p> <p>24 happens to be pharmacies that are in Ohio,</p>
<p style="text-align: right;">Page 539</p> <p>1 MR. LEEDER: Object to form.</p> <p>2 BY MR. YOUNG:</p> <p>3 Q. Do you recall that project?</p> <p>4 A. I recall looking at -- I'm not</p> <p>5 sure of the exact details, but I recall looking</p> <p>6 at some orders that -- that that did occur with.</p> <p>7 Q. All right. I'm going to quickly</p> <p>8 direct your attention to my Exhibit 18. It will</p> <p>9 be this deposition's Exhibit 30.</p> <p>10 (Document marked for</p> <p>11 identification as Par-Norton Deposition</p> <p>12 Exhibit No. 30.)</p> <p>13 BY MR. YOUNG:</p> <p>14 Q. It's a -- it's a one page e-mail</p> <p>15 with a colored spreadsheet behind it. I got a</p> <p>16 copy for you coming.</p> <p>17 Do you recall this cover e-mail?</p> <p>18 A. I do.</p> <p>19 Q. And you were cc'd on this. This</p> <p>20 is from Kyle Rieger to Durga -- I don't know how</p> <p>21 you pronounce it, I say Jarugula, kind of like</p> <p>22 the lettuce?</p> <p>23 A. Yes.</p> <p>24 Q. And the subject is CSOMP</p>	<p style="text-align: right;">Page 541</p> <p>1 northern Ohio or a pharmacy in northern Ohio,</p> <p>2 this is just an example, but what I'm interested</p> <p>3 in is the pink highlighted row H.</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. So where it says "Shipped Over</p> <p>7 URL," what do you understand that to mean?</p> <p>8 MR. LEEDER: Objection to form.</p> <p>9 THE WITNESS: Those are over</p> <p>10 the -- over the plant -- plant assigned</p> <p>11 limit.</p> <p>12 BY MR. YOUNG:</p> <p>13 Q. So let's just take the 4200</p> <p>14 number in row 34 there. It says "Shipped Over</p> <p>15 URL 4200." What is 4200, is that DUs?</p> <p>16 A. Dosage units.</p> <p>17 Q. Okay. And can you tell, I don't</p> <p>18 know if you recall from this, what drug we're</p> <p>19 referring to where it says family 220?</p> <p>20 A. I don't recall.</p> <p>21 Q. And then there's a column next to</p> <p>22 it that says, "Did any orders bypass CSOMP?"</p> <p>23 And the answer in this case is?</p> <p>24 A. Yes.</p>

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<p style="text-align: right;">Page 542</p> <p>1 Q. Yes. And in the entire 2 spreadsheet, in fact, the answer is yes; is that 3 correct? 4 MR. LEEDER: Objection to form. 5 THE WITNESS: Yes, that's 6 correct. 7 BY MR. YOUNG: 8 Q. I don't know if there's a -- on 9 the next page of that spreadsheet, is there a 10 total number of DUs? I don't know if it totals 11 it at the top? It might not. Maybe the last 12 page of it, does it total it on the last page? 13 A. Yes. 14 Q. Can you read for me what that 15 total number of DUs is for this one month in 16 2014 that shipped from HD Smith over the URL? 17 A. 530,282. 18 Q. Dosage units? 19 A. Yes. 20 Q. In one month? 21 A. Yes. 22 Q. Does that seem like a lot of 23 controlled substance to go out the door without 24 being investigated under the CSOMP?</p>	<p style="text-align: right;">Page 544</p> <p>1 tomorrow 8:30 a m. 2 MR. BUCHANAN: We've confirmed 3 that we're commencing at 8:30 and we'll 4 conclude by noon. So defendants will 5 keep their examinations tailored and 6 breaks tailored to accommodate that 7 timing, and plaintiffs will do so as 8 well. 9 (Witness excused.) 10 --- 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>
<p style="text-align: right;">Page 543</p> <p>1 MR. LEEDER: Where are we on 2 time, I'm sorry, but -- it's 7:00? 3 MR. YOUNG: Are you ceasing the 4 depo now? 5 MR. LEEDER: That's fine, she can 6 answer the question. 7 THE WITNESS: I can't answer a 8 lot. That's subjective. 9 MR. YOUNG: Okay. At this point 10 counsel is directing we've run out of 11 time in the examination, so I don't have 12 any further questions for you. 13 THE VIDEOGRAPHER: This concludes 14 the deposition, going off the record at 15 6:25. This concludes this portion of 16 the deposition at 6:25 p m. Going off 17 the record. 18 (Off the video record.) 19 MS. VANNI: We are keeping the 20 deposition open until tomorrow in that 21 defendants want to conduct direct 22 examinations of the witness followed by 23 cross. And cross-examination for today 24 is done, and we will start with direct</p>	<p style="text-align: right;">Page 545</p> <p>1 C E R T I F I C A T I O N 2 I, MARGARET M. REIHL, a 3 Registered Professional Reporter, 4 Certified Realtime Reporter, Certified 5 Shorthand Reporter, Certified LiveNote 6 Reporter and Notary Public, do hereby 7 certify that the foregoing is a true and 8 accurate transcript of the testimony as 9 taken stenographically by and before me 10 at the time, place, and on the date 11 hereinbefore set forth. 12 I DO FURTHER CERTIFY that I 13 am neither a relative nor employee nor 14 attorney nor counsel of any of the 15 parties to this action, and that I am 16 neither a relative nor employee of such 17 attorney or counsel, and that I am not 18 financially interested in the action. 19 20 21 ----- 22 Margaret M. Reihl, RPR, CRR, CLR 23 CSR #XI01497 Notary Public 24</p>

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<div style="text-align: right; margin-bottom: 10px;">Page 546</div> <div style="text-align: center; margin-bottom: 10px;"> <p>1                   - - - - -</p> <p>2                   E R R A T A</p> <p>3                   - - - - -</p> </div> <div style="margin-bottom: 10px;"> <p>4   PAGE LINE CHANGE</p> </div> <div style="margin-bottom: 10px;"> <p>5   _____</p> <p>6   REASON: _____</p> <p>7   _____</p> <p>8   REASON: _____</p> <p>9   _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p> </div>	
<div style="text-align: right; margin-bottom: 10px;">Page 547</div> <div style="text-align: center; margin-bottom: 10px;"> <p>1                   ACKNOWLEDGMENT OF DEPONENT</p> </div> <div style="margin-bottom: 10px;"> <p>2</p> <p>3                   I, TRACEY L. NORTON, do hereby</p> <p>4                   certify that I have read the foregoing</p> <p>5                   pages, and that the same is a correct</p> <p>6                   transcription of the answers given by me</p> <p>7                   to the questions therein propounded,</p> <p>8                   except for the corrections or changes in</p> <p>9                   form or substance, if any, noted in the</p> <p>10                  attached Errata Sheet.</p> <p>11</p> <p>12</p> <p>13</p> </div> <div style="margin-bottom: 10px;"> <p>14   _____ TRACEY L. NORTON                   DATE</p> </div> <div style="margin-bottom: 10px;"> <p>15   Subscribed and sworn to before me this</p> <p>16   _____ day of _____, 2018.</p> <p>17   My commission expires: _____</p> </div> <div style="margin-bottom: 10px;"> <p>18   _____ Notary Public</p> </div> <div style="margin-bottom: 10px;"> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> </div>	